Supreme Court, U.S.
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No. _____

In The
Supreme Court of the United States
October Term 1998

ANN WARDER, et al.,

Petitioners,

V.

DONNA E. SHALALA, et al.,

Respondent.

On Petition For A Writ of Certiorari
To the United States Court of
Appeals For the First Circuit

APPENDIX TO PETITION FOR A WRIT OF CERTIORARI

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United States Court of Appeals
For the First Circuit

No. 97-2047

ANN WARDER, ET AL.,

Plaintiffs, Appellees,

v.

DONNA E. SHALALA, ET AL.,

Defendants, Appellants.

APPEAL FROM THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

[Hon. Morris E. Lasker,*
U.S. District Judge]

Before
Torruella, Chief Judge,

Campbell, Senior Circuit Judge,

and Lynch, Circuit Judge.

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*Of the Southern District of New York, sitting by designation.

Clifford M. Pierce, Assistant Regional Counsel, Department of Health and Human Services, with whom Frank W. Hunger, Assistant Attorney General, Department of Justice, Harriet S. Rabb, General Counsel, and Nancy S. Nemon, Chief Counsel, Region I, Department of Health and Human Services, were on brief for appellants.

James P. Kelly with whom Patrick M. Connolly, Kelly Law Firm, Craig E. Stewart, Anne Robbins and Palmer & Dodge LLP were on brief for appellees.

July 27, 1998

CAMPBELL, Senior Circuit Judge. This appeal relates to the classification, for Medicare Part B reimbursement purposes, of medical equipment made for persons suffering from severe musculoskeletal problems. Produced by Appellees OrthoConcepts and used by Appellee Warder, the equipment consists of braces, fitted to the individual patient, on a wheeled base. The district court upheld OrthoConcepts' challenge to an administrative ruling ("the Ruling" or "HCFAR 96-1") from the Health Care Financing Administration ("HCFA") that classifies this equipment as "durable medical equipment" rather than as "braces." The former classification limits Medicare reimbursement to devices used at home, precluding reimbursement for such devices when used in certain hospital and institutional settings.

Holding that HCFAR 96-1 was a substantive, or legislative, rule requiring notice and comment, the court

ruled it to be invalid because notice and comment procedures had not been followed prior to its issuance. The court also found that the equipment in dispute was not "durable medical equipment," and enjoined HCFA from treating it as such.

We disagree. We hold that HCFAR 96-1 is an interpretive rule, and was not invalidated by HCFA's failure to have adopted notice and comment procedures. We vacate the injunction on the ground that HCFA's interpretation was a permissible one.

BACKGROUND

1. Statutory and Regulatory Background

A. Part B of the Medicare Act

The Medicare Act, 42 U.S.C. § 1395 et seq., establishes a national health insurance program for the elderly and the disabled. Congress authorized Appellant Secretary of Health and Human Services to implement the Medicare statute by issuing both substantive regulations and interpretive rules. See 42 U.S.C.

§1395hh. The Secretary has in turn delegated this authority to the HCFA Administrator.

Part B of the Medicare Act, 42 U.S.C. § 1395j et seq., establishes a voluntary supplemental insurance program. Eligible individuals enrolled in the program pay a monthly premium that, along with congressionally appropriated funds, finances physicians' and other health services. See id. § 1395j. Part B has been referred to as "a private medical insurance program that is subsidized in major part by the Federal Government." Schweiker v. McClure, 456 U.S. 188, 190 (1982).

Part B benefits are administered by private insurance carriers under contract with HCFA. See 42 U.S.C. §1395u. HCFA reimburses a carrier for the costs of administering claims, and the carriers act as HCFA's agents. See id. §1395u(a); 42 C.F.R. § 421.5(b). The carrier bears the initial responsibility for determining whether an item or service billed to the Part B program is covered

and, if so, the amount to be paid. See 42 U.S.C. §1395u.

B. Part B Coverage of DME and Braces

Medicare Part B provides coverage for "medical and other health services," 42 U.S.C. §1395x(s), that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member," id. §1395y(a)(1)(A). The statute expressly covers braces, including "leg, arm, back, and neck braces." Id. §1395x(s)(9).

Ordinarily, coverage will extend to any piece of equipment that is reasonable and necessary for the treatment of an eligible patient regardless of the place where it is used. However, Part B reimburses devices classified as "durable medical equipment" ("DME") only when provided at the patient's "home" or other "institution used as [the patient's] home," and not in a hospital or skilled nursing facility ("SNF"). 42 U.S.C.

§1395x(n) (citing §§1395x(e)(1) (defining hospital), 1395i-3(a)(1) (defining SNF))[1] (1). In other words, DME is reimbursable only when used in a patient's home, with "home" being defined to exclude hospitals and SNFs.

No similar restriction relates to "braces." See 42 U.S.C. §1395x(s)(9). Hence if a piece of medical equipment used in a hospital or SNF is a "brace," it is reimbursable — but not if deemed to be DME.

C. DME and Braces Defined

The medical device here, intended for persons with severe musculosekeletal failure, includes a set of connected braces attached to a wheeled base. See infra. While various provisions define

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1. See also, 42 C.F.R. § 410.38(a), (b) (explaining that "Medicare Part B pays for [DME], if the equipment is used in the patient's home or in an institution that is used as a home" and that "[a]n institution that is used as a home may not be a hospital or a critical access hospital as defined at 42 U.S.C. § 1395x(mm)] or a SNF").

braces and DME, no single provision concisely differentiates the two, leaving it open which category is implicated when, as here, a brace-like device is used as part of a wheeled item that might be classified as DME.

The principal statutory definition of DME states that "[DME] includes iron lungs, oxygen tents, hospital beds, and wheelchairs." 42 U.S.C. §1395x(s)(6) (emphasis supplied). Elsewhere the statute includes special payment provisions for certain types of DME, including "items requiring frequent and substantial servicing," id. §1395m(a)(3), and equipment customized to an individual patient's needs, see id. §1395m(a)(4). However, neither of these provisions can be read to expand §1395x(s)(6)'s definition of DME, because both are expressly limited to a subset of DME. See id. §1395m(13) (defining "covered item[s]" under §1395m to be DME "as defined in section 1395x(n)").

In 1990, Congress amended §1395m(a)(4) to add a provision -- which

ultimately, by its own terms, was superseded by a HCFA regulation -- expressly providing that customized wheelchairs were DME. P.L. 101-508, §4152(c)(4)(B).[2] The amendment provided that it would become effective on January 1, 1992, unless HCFA developed its own criteria for the treatment of customized wheelchairs as DME. In December, 1991, HCFA addressed customized wheelchairs in a regulation that substantially tracked the language of the amendment, providing that a wheelchair is DME if "uniquely constructed or substantially modified for a specific beneficiary" and "so different from another item used for the same purpose that the two items cannot be grouped together for pricing purposes." 42 C.F.R. §414.224. In effect, Congress, and subsequently HCFA, treated as DME any

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2. The amended definition of DME included any wheelchair "measured, fitted, or adapted in consideration of the patient's body size, disability, period of need, or intended use, and ... assembled by a supplier ... who makes available customized features, modifications, or components for wheelchairs that are intended for an individual patient's use in accordance with instructions from the patient's physician." P.L. 101-508, § 4152(c)(4)(B).

wheelchair modified in light of an individual patient's disability, per a physician's instructions.

The regulatory definition of DME focuses not on examples, but rather on qualitative criteria, including the equipment's durability:

equipment, furnished by a supplier or a home health agency that --

(1) Can withstand repeated use;

(2) Is primarily and customarily used to serve a medical purpose;

(3) Generally is not useful to an individual in the absence of an illness or injury; and

(4) Is appropriate for use in the home [citing 42 C.F.R. §410.38, which in turn cites statutory provisions defining "home" to exclude

hospitals and SNFs].

42 C.F.R. §414.202.

The manual HCFA prepares for its carriers repeats the regulatory criteria. See Medicare Carrier's Manual ("MCM") §2000.1. Another provision in the manual goes farther, explaining that DME includes "supplies and accessories" that are "necessary for the effective use of [DME]." MCM, §2100.5.

The statutory definition of "brace" is ostensive, listing the sorts of braces that are covered. Id. § 1395x(s)(9) (defining orthotics as "leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including requirements if required because of a change in the patient's physical condition"). The accompanying regulation, 42 C.F.R. § 414.202, tracks the statutory language.

2. The OrthoConcepts Product

Due to illness, injury, and in some cases old age, thousands of Medicare

beneficiaries suffer from musculoskeletal failure so severe as to render them incapable of moving or supporting their own limbs. These catastrophically crippled patients are vulnerable to numerous painful conditions. One of the most serious is contractures, a condition in which muscles become rigid and resistant to elongation following a long period of disuse. See Dorland's Illustrated Medical Dictionary 373 (28th ed. 1994). Other complications include the development of pressure sores, circulatory problems, and infections.

To manage the condition of patients with grave musculoskeletal failure, OrthoConcepts designed what it has marketed as the "OrthoConcepts Seating System." The Seating System consists of a set of connected braces -- the number and type depending on the patient's condition -- attached to a wheeled base. The patient sits, or reclines, on the Seating System, and the component braces maintain the patient in a position designed to reduce the weight borne by weaker extremities and to prevent

contractures. Since 1989, OrthoConcepts has supplied the Seating System to more than 2700 patients.

3. HCFA's Classification of the OrthoConcepts Seating System

On December 7, 1989, OrthoConcepts informed a regional HCFA office that OrthoConcepts would soon begin marketing the Seating System nationwide. OrthoConcepts' letter inquired about the Medicare coverage status of the Seating System and asked HCFA to establish a new billing code (known as a "L code," a standardized billing classification for "orthotics," or braces) that would allow the Seating System to be reimbursed as a brace. The regional office replied in January of 1990, advising OrthoConcepts that Part B covered the Seating System as DME, not as orthotics, and that it would provide no L Code for billing the Seating System as an orthotic.

The regional office also wrote its private carriers regarding the Seating System, instructing them to treat the

device as DME. By letter dated February 21, 1990, the carrier then responsible for OrthoConcepts' claims, Nationwide Insurance, notified OrthoConcepts of the HCFA regional office's letter and informed it that its products "are classified as [DME]; not orthotics."

In late 1992, HCFA reorganized its system for processing claims for DME and orthotics, replacing local carriers with four regional carriers known as "DMERCs." HCFA instructed the DMERCs to issue uniform reimbursement policies. In August, 1993, the DMERCs announced that they would reimburse certain orthotic seating systems (known by the billing designations or "K-codes" as K-0115 and K-0116) as braces. These seating systems were functionally quite similar to the OrthoConcepts Seating System, differing principally in that they were fitted using a plaster cast of the individual patient rather than the manually-adjusted attachments that are part of the Seating System. The following April, after learning of this billing practice, HCFA informed the DMERCs that K-codes 0115 and

0116 described DME, not orthotics. The DMERCs in turn notified their respective suppliers of HCFA's determination.

Despite HCFA's 1990 letter declaring the Seating System DME, OrthoConcepts, through its corporate affiliates, continued to bill Seating Systems supplied to patients at SNFs as an orthotic. Upon learning of this practice, HCFA's Region A DMERC suspended Medicare payments to OrthoConcepts in December, 1994. Following a meeting with OrthoConcepts representatives and an inspection of SNFs where the Seating System was in use, one of the carriers concluded that the billed equipment was in fact DME, and notified the OrthoConcepts affiliates that it was obligated to refund the Part B payments. Soon thereafter, the Region B and Region C DMERCs denied OrthoConcepts reimbursement.

OrthoConcepts appealed from the carriers' denials of their Part B

claims.[3] In the Region A appeal, a Part B hearing officer issued a decision on August 30, 1995, finding that the Seating System was DME and concluding that Part B did not provide reimbursement for the disputed claims. However, after an ex parte hearing, an ALJ reversed the hearing officer's decision on January 3, 1996, ruling that the Seating Systems "[were] orthotic braces and not

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3. To receive reimbursement of past medical expenditures or pre-payment of expected costs, the beneficiary of the expenditures (or a "supplier of services" that has accepted assignment of the beneficiary's claim) must request payment from HCFA' designated carrier. See 42 U.S.C. § 1395u(a) (granting authority to utilize private insurance carriers for administration of Part B claims). Each carrier contract must require the carrier to provide a "fair hearing" for suppliers whose claims are denied and that meet an amount-in-controversy requirement. See id. § 1395u(b)(3)(C).

If dissatisfied with the result of the fair hearing, the beneficiary or supplier may appeal to an Administrative Law Judge and, if necessary, to the Department Appeals Board. See id. § 1395ff(b)(2)(B). Judicial review of an adverse Appeals Board decision may be obtained if the amount in controversy is one thousand dollars or more and the beneficiary or supplier files a district court action within sixty days. See id. § 1395ff(b)(1), (b)(2)(B).

wheelchairs." On March 1, 1996, the Appeals Board denied HCFA's petition to review the ALJ's decision.

The Region B and Region C appeals were consolidated before a carrier fair hearing officer. On February 9, 1996, the hearing officer decided that the Seating System was an orthotic device rather than DME. This ended the matter, as the statute gives HCFA no administrative appeal from a hearing officer's adverse decision.

The net result of these proceedings was that by early 1996, HCFA's view of the Seating System as DME - as expressed in its 1990 letter to OrthoConcepts and its 1994 notice to its carriers - was at odds with the decisions of an ALJ and a hearing officer.

These decisions prompted HCFA to issue HCFAR 96-1, which became effective September 18, 1996. Noting the above-mentioned decisions classifying the Seating System as an orthotic, the Ruling's stated purpose is "to provide

clarification and guidance regarding the scope and meaning of the statutory benefits for 'orthotics' and '[DME].'" HCFAR 96-1 at 2. The Ruling discusses the relevant statutes, regulations, legislative history, and administrative materials before reaching its conclusion: the definition of "orthotics" "is limited to leg, arm, back, and neck braces that are used independently [of], rather than in conjunction with, or as components of, other kinds of medical equipment." Id. at 10. The Ruling also provides several illustrations of DME, one of which unmistakably refers to the OrthoConcepts Seating System. See id. at 7-8.

On February 26, 1997, two Medicare beneficiaries who used the Seating System in SNFs and three OrthoConcepts suppliers (hereinafter, Appellees will be referred to collectively as "OrthoConcepts") brought the present district court action challenging HCFAR 96-1. Appellees advanced the procedural claim that HCFAR 96-1 was invalid, having been adopted without compliance with the notice-and-comment procedures of the Administrative

Procedure Act ("APA"), 5 U.S.C. § 553, and the Medicare statute, 42 U.S.C. § 1395hh. Appellees also made the substantive claim that HCFAR 96-1 was arbitrary and capricious, see 5 U.S.C. § 706(2)(A). Appellees sought a declaration that the Ruling was void and that the Seating System was reimbursable as a brace. They also requested a preliminary injunction blocking HCFA from enforcing the Ruling.

After holding a hearing on Appellees' motion for a preliminary injunction, the district court notified the parties that it would issue a final determination on the merits of Appellees' claims. On March 7, 1997, the district court ruled that HCFAR 96-1 is a substantive rule and, therefore, invalid because HCFA issued it without following notice and comment procedures. The court went on to hold that, the definitions of DME and orthotics in effect prior to the Ruling prevented HCFA from treating the Seating System as DME. (The court left open the possibility that HCFA could validly re-enact the Ruling after using

notice and comment procedures.) The court also enjoined HCFA from denying Appellees reimbursement for the Seating System.

This appeal followed.

DISCUSSION

1. The Interpretative Rule Exception to the Requirement of Notice and Comment

Whether an administrative ruling is substantive or interpretative is a question of law that this court reviews de novo. See La Casa Del Convaleciente v. Sullivan, 965 F.2d 1175, 1177 (1st Cir. 1992) ("Convaleciente").

The APA exempts "interpretative rules" from its notice and comment procedures. 5 U.S.C. § 553(b)(B). The Medicare Act expressly incorporates the APA's exemption for interpretive rules.

See 42 U.S.C. § 1395hh(b)(2)(C) (1994).[4]

The line between a legislative or substantive rule and an interpretative one is, as many courts have noted, far from clear. See, e.g., Convaleciente, 965 F.2d at 1177. The APA itself does not define "substantive" and "interpretive" (or, in the APA's nomenclature, "interpretative") rules. Moreover, courts and other authorities have provided any number of definitions, lending further imprecision to the field. Nevertheless, a few reasonably clear principles have emerged, leading us to conclude that HCFAR 96-1 is interpretative, and could be promulgated without notice and comment procedures.

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4. The Social Security Act ("SS"), of which the Medicare statute is part, phrases the distinction between substantive and interpretive rules slightly differently from the APA, requiring notice and comment procedures for any rule "that established or changes a substantive legal standard governing the scope of benefits," 42 U.S.C. § 1395hh(a)(2), but exempting by implication, inter alia, "interpretive rules," id. § 1395hh(c) (requiring periodic publication of "interpretive rules" that have not been issued as regulations.

The most authoritative explanation of the substantive/interpretative distinction is that provided by the Attorney General's Manual on the Administrative Procedure Act (1947).[5] The Attorney General's Manual described an interpretive rule as one "issued by an agency to advise the public of the agency's construction of the statutes and rules which it administers." Id. at 30 n.3. Courts have routinely quoted this definition with approval. See Shalala v. Guernsey Memorial Hosp., 514 U.S. 87, 99 (1995); Chrysler Corp. v. Brown, 441 U.S. 281, 302 n.31 (1979); Convaleciente, 965 F.2d at 1178. The Attorney General's Manual defines substantive, or legislative, rules as those that are issued by an agency pursuant to statutory

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5. See Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, Inc., 435 U.S. 519, 546 (1978)(describing the Attorney General's Manual as "a contemporaneous interpretation [of the APA] previously given some deference by this Court because of the role played by the Department of Justice in drafting the legislation").

authority and which implement the statute [such as the Securities and Exchange Commission's proxy rules issued pursuant to the Securities Exchange Act of 1934, 15 U.S.C. § 78n(b)]. Such rules have the force and effect of law.

Id.

These definitions have caused us to observe "that the distinction between legislative and interpretative rules has to do in part with the authority" -- law-making versus law-interpreting -- "under which the rule is promulgated." Levesque v. Block, 723 F.2d 175, 182 (1st Cir. 1982). The Seventh Circuit has stated that "rules are legislative when the agency is exercising delegated power to make law through rules, and rules are interpretative when the agency is not exercising such delegated power in issuing them." Metropolitan Sch. Dist. v. Davila, 969 F.2d 485, 490 (7th Cir. 1992).

Where a rule falls along the interpretative/legislative spectrum will turn in many cases on the novelty of a

rule's substantive content. "If a rule creates rights, assigns duties, or imposes obligations, the basic tenor of which is not already outlined in the law itself, then it is substantive." Convaleciente, 965 F.2d at 1178 (emphasis supplied); see also American Mining Congress v. Mine Safety & Health Admin., 995 F.2d 1106, 1112 (D.C. Cir. 1993) (stating that a rule is legislative if "in the absence of the rule there would not be an adequate legislative basis for enforcement action or other agency action to confer benefits or ensure the performance of duties"). Put more succinctly, a rule is exempt from notice and comment as an interpretative rule if it does not "effect a substantive change in the regulations." Guernsey, 514 U.S. at 100 (internal quotation marks and citation omitted).

On its face, HCFAR 96-1 appears to satisfy the criteria for an interpretive rule. We have said that an important factor in determining whether a rule is interpretive is the agency's own characterization. See Convaleciente, 965

F.2d at 1178; Levesque, 723 F.2d at 182. It is not disputed that HCFA intended HCFAR 96-1 to be interpretative. The Ruling itself purports only to "clarify" the proper application of existing statutory and regulatory definitions to a particular case.[6]

More importantly, the Ruling does not establish any new standard. Rather, it addresses an area of ambiguity:

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6. In Levesque we stated that the impact of a rule on the regulated parties "may be relevant in construing the intent of the agency is issuing the rule." 732 F.2d at 182. Both sides have acknowledged that the Seating System's reimbursement classification had public importance. However, where, as here, the agency's intent is unambiguous, a rule's impact on the public ceases to be of possible significance in construing agency intent.

Indeed, this Circuit's law regarding the relevance of a rule's public impact is in doubt. We did not give the substantial impact factor any weight in Convaleciente, see 965 F.2d at 1178 (noting that other circuits have treated public impact as irrelevant), and the Supreme Court wholly ignored it in Guernsey and in Reno v. Koray, 515 U.S. 50 (1995) (characterizing as interpretative a rule affecting prisoners credit for time served), two cases that each involved a rule with an apparently substantial public impact.

whether a device comprising both orthotic and DME components should be reimbursed as a brace or as DME. The statutory and regulatory definitions of DME and orthotics predated the Ruling, but neither was so complete as to provide an unambiguous answer to the question of the Seating System's classification.[7] These definitions created the need for clarification -- precisely the function of an interpretative rule -- and they

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7. The pre-Ruling ambiguity of the Seating System's proper classification is what distinguishes this case from Linoz v. Heckler, 800 F.2d 871 (9th Cir. 1986), upon which OrthoConcepts relies heavily. In Linoz, the court considered a change to the MCM instructing carriers that coverage of ambulance trips to the "nearest hospital with appropriate facilities" did not include trips "solely to avail a patient of the service of ... a physician in a specific specialty." See id. at 876, The Linoz court held that the limitation imposed by the new provision "withdrew coverage previously provided," id. at 877, therefore changing substantive law.

Unlike the rule in Linoz, which altered rather than clarified the coverage of ambulance trips, HCFAR 96-1 does not "carve[] out a per se exception" to a rule that previously provided exceptions. Id. Instead, the Ruling explicates the view that the existing statutory and regulatory definitions place certain equipment in one existing category instead of another.

provided an "adequate legislative basis for [the agency action]." American Mining Congress, 995 F.2d at 1112. The Ruling does not stake out any ground "the basic tenor of which [was] not already outlined in the law itself." Convaleciente, 965 F.2d at 1178.

We find guidance in the Supreme Court's recent Guernsey decision. There, the Court considered whether the interpretative rule exemption applied to an accounting provision in HCFA's Provider Reimbursement Manual ("PRM"). Like HCFAR 96-1, the PRM provision at issue in Guernsey "[did] not purport to be a regulation and [had] not been adopted pursuant to the notice-and-comment procedures of the [APA]." 514 U.S. at 90. The Court determined that the PRM provision concerned "[t]he only question unaddressed by the otherwise comprehensive regulations on this particular subject." Id. at 97. The Court concluded that the measure "[was] a prototypical example of an interpretive rule" because the PRM provision merely applied existing law, id. at 99, and was

not "inconsistent with any of the Secretary's existing regulations," id. at 100.

The reasoning in Guernsey applies here. The Medicare statute and regulations provide a comprehensive classification of equipment as DME or orthotics. The Ruling addresses a small overlap in this scheme. The answer the Ruling provides is consistent with the existing definitions. The statute and regulations define braces only by referring to particular types of braces, none of which would have to include a system of braces attached to a wheeled base. See 42 U.S.C. § 1395x(s)(9). But clearly the Seating System fits within one category or the other, so HCFA was acting in an interpretive, rather than legislative, capacity. See United Technologies Corp. v. EPA, 821 F.2d 714, 719-20 (D.C. Cir. 1987) ("If the rule is based on specific statutory provisions, and its validity stands or falls on the correctness of the agency's interpretation of those provisions, it is an interpretative rule.").

By the same token, the Ruling is not inconsistent with existing law because the statutory and regulatory definitions of DME are broad enough to include the Seating System. It is conceded that the Seating System "[c]an withstand repeated use," 42 C.F.R. § 414.202, a principal regulatory criterion differentiating DME from other equipment. Moreover, it is not inconsistent to treat the Seating System -- which is, after all, a wheeled device in which a patient sits -- as a customized wheelchair, a piece of equipment specifically identified as DME. See 42 U.S.C. § 1395x(n); 42 C.F.R. § 414.224. Nothing in any of the existing statutory or regulatory definitions is inconsistent with HCFAR 96-1. Together, the extant definitions were ambiguous in respect to the category within which the Seating System best fit, and "the quintessential example of an interpretive rule" is "[a] statement seeking to interpret a statutory or regulatory term." Orengo Carballo v. Reich, 11 F.3d 186, 195 (D.C. Cir. 1993).

OrthoConcepts' main contention both in the district court and on appeal was that HCFAR 96-1 was legislative because it changed HCFA's policy of reimbursing the Seating System as DME. This argument rests on erroneous views of both the law and the facts.

The legal point is clear enough: in order for notice and comment to be necessary, "the [later] rule would have to be inconsistent with another rule having the force of law, not just any agency interpretation regardless of whether it had been codified." Chief Probation Officers v. Shalala, 118 F.3d 1327, 1337 (9th Cir. 1997) (White, J. (Retired, sitting by designation)). The Supreme Court in Guernsey intimated this much, concluding that the provision there was interpretive because it did not contradict "any of the Secretary's existing regulations." 514 U.S. at 100 (emphasis supplied); see also id. at 111 (O'Connor, J., dissenting) (observing that interpretive rules "must explain existing law and not contradict what the [extant] regulations require"). The

lower federal courts are in agreement on this score. See, e.g., Orengo, 11 F.3d at 196 (explaining that a subsequent rule is legislative "[o]nly where [the] second rule repudiates or is irreconcilable with [a prior legislative rule]"); White v. Shalala, 7 F.3d 296, 304 (2d Cir. 1993) ("If the rule is an interpretation of a statute rather than an extra-statutory imposition of rights, duties or obligations, it remains interpretive even if the rule embodies the Secretary's changed interpretation of the statute."); Davila, 969 F.2d at 492 ("[A]n agency's change in its reading of the statute does not necessarily make the rule announcing the change legislative."). As already stated, see supra, nothing in the statute or regulations addresses the precise issue decided in HCFAR 96-1. Thus, even supposing HCFA's pre-Ruling policy was different, the earlier policy would not prevent HCFA from adopting a contrary new interpretative rule.

However, we very much doubt that the Ruling, by limiting the coverage of braces to devices used independently of

DME, added something new to HCFA's policies. In siding with OrthoConcepts, the district court concluded that the agency's informal pronouncements and practices regarding the reimbursement of the Seating System indicated a pre-Ruling policy to treat the Seating System as an orthotic. A number of factors, however, suggest the opposite conclusion.

First, the HCFA regional office's 1990 letter to OrthoConcepts specifically stated that the Seating System was DME. The district court disregarded this letter because a former OrthoConcepts attorney submitted an unsworn affidavit stating that the office promised to issue a letter rescinding the corresponding order instructing its carriers to treat the Seating System as DME. However, as the district court found, "there is no evidence that HCFA ever sent such a letter," nor is there any evidence corroborating the unsworn affidavit.

Second, HCFA instructed its carriers on three separate occasions that devices quite similar to the Seating System

should be treated as DME. The first two memoranda, issued in 1987 and 1989, dealt with "contoured corrective seats," and concluded, as the 1989 memorandum put it, that the "only statutory provision that could apply to such equipment" was DME. The district court dismissed these memoranda on the ground that, by questioning whether the devices served a medical purpose, they relied on an alternative basis for denying the contoured corrective seats coverage. However, we cannot see how the inclusion of this complementary argument contradicts or negates the independent conclusion that the equipment at issue was DME.

A further manifestation of HCFA's earlier policy was its 1994 instruction to treat as DME equipment designated by the K-codes 0115 and 0116. The district court dismissed the 1994 instruction as "not directly on point," but the instruction set out a policy for equipment that, like the Seating System and the first illustration given in HCFAR 96-1, contained orthotic attachments.

While the 1994 instruction addressed equipment with a different technical design, it implicitly contained the same principle as the Ruling: DME includes orthotic components that cannot be used independently of attached DME. That the 1994 instruction (as well as the 1987 and 1989 memoranda) did not address the precise equipment at issue here does not mean that HCFA had no relevant policy: "an interpretive statement may 'suppl[y] crisper and more detailed lines than the authority being interpreted.'" Orengo, 11 F.3d at 195 (quoting American Mining Congress, 995 F.2d at 1112). Thus, we reject OrthoConcepts' contention that HCFAR 96-1 effected a substantive change in the regulations.

As a fallback position, OrthoConcepts argues that HCFAR 96-1 could not be valid without notice-and-comment rulemaking because it has a binding effect on agency personnel. This argument confuses two senses in which a rule may bind. Of course, a rule with the force and effect of law -- binding not only the agency and regulated

parties, but also the courts -- is by definition a substantive rule. However, a rule may lack this force and still bind agency personnel. Accordingly, "[a]n interpretative rule binds an agency's employees, including its ALJs, but it does not bind the agency itself." Kenneth C. Davis & Richard J. Pierce, Jr., Administrative Law Treatise § 6.3 at 104 (3d ed. 1996 & Supp. 1997). In other words, a rule may be "binding" but not, for purposes of notice and comment, "substantive," or legislative. We rejected an argument almost identical to OrthoConcepts' in Levesque: "If plaintiffs mean that any rule that an agency intends to be effective must be legislative, they are plainly wrong. Every rule is intended to have some effect." 723 F.2d at 181-82; see also American Mining Congress, 995 F.2d at 1111 ("[R]estricting discretion tells one little about whether a rule is interpretive."); Davila, 969 F.2d at 493 ("All rules which interpret the underlying statute must be binding because they set forth what the agency believes is congressional intent."). The

fact that the Ruling binds HCFA carriers and ALJs is entirely consistent with its status as an interpretative rule.

We therefore reject OrthoConcepts' argument that HCFAR 96-1 was not legally adopted because of the absence of notice and comment procedures.

2. Injunction

The district court enjoined the Secretary from enforcing the Ruling and from denying OrthoConcepts' reimbursement for its Seating System under the braces benefit. It granted this relief based on the erroneous belief, supra, that HCFAR 96-1 was invalidly promulgated, leaving HCFA without an adequate basis for treating the Seating System as DME. As held above, however, HCFAR 96-1 was properly promulgated; we now further hold that the Ruling's interpretation of the Seating System as DME is adequately supported by the Medicare statute and regulations. We therefore vacate the injunction.

A threshold question is what deference is owed to an interpretative rule such as HCFAR 96-1. The Supreme Court has not expressed a view on whether or to what extent the Chevron framework, see Chevron, U.S.A., Inc. v. Natural Resources Defense Council, 467 U.S. 837 (1984), applies to interpretive, rather than legislative rules, and other circuits are split on the issue.[8]

We need not decide the issue here because, even assuming arguendo that Chevron deference is not applicable to interpretative rules, we are persuaded

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8. Compare Trans Union Corp. v. FTC, 81 F.3d 228, 230 (D.C. Cir. 1996)("[W]e have extended Chevron deference to agency interpretive rules ... indeed, the rule at issue in Chevron itself appears to have been interpretive."), and Elizabeth Blackwell Health Ctr. For Women v. Knoll, 61 F.3d 170 (3d Cir. 1995) (equal deference), and Garcia v. Secretary of Health & Human Servs., 46 F.3d 552, 557 (6th Cir. 1995)(same), with Atchison, Topeka & Santa Fe Ry. Co. v. Pena, 44 F.3d 437, 442 (7th Cir. 1994) (en banc)(concluding that interpretive rules are "undeserving of deference under Chevron"); see generally Davis & Pierce, supra, § 3.5 (discussing ambiguity).

that HCFAR 96-1 is an appropriate construction of the statute. We are guided in this regard by Skidmore v. Swift & Co., 323 U.S. 134 (1944). There, the Court considered a rule that, having been issued by an agency not authorized to make legislative rules, was necessarily interpretative and without the force of law. See id. at 138. The Supreme Court approved the agency's interpretation and explained the proper approach to judicial review of interpretative rules:

> [T]he rulings, interpretations and opinions of the Administrator under this Act, while not controlling upon the courts by reason of their authority, do constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance. The weight of such a judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of

> its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control.

323 U.S. at 140. Considering all of these factors, we think the interpretation embodied in HCFAR 96-1 is wholly supportable.

First, as already discussed, see supra, HCFAR 96-1 is generally consistent with HCFA's earlier informal pronouncements. See Alessi v. Raybestos-Manhattan, Inc., 451 U.S. 504, 517 n.13 (1981) (describing "scrutiny applicable to interpretive rules" as involving "due deference to consistent agency practice"). Hence to the extent that inconsistency with prior policies might lead us to find an interpretative rule arbitrary or capricious, we see no inconsistencies of such a nature.

Second, we find the Ruling to be a persuasive reading of the statute and

HCFA's regulations. Those materials establish three criteria for classifying a device as DME: the item must be "durable," i.e., able to "withstand repeated use"; it must be reasonably necessary "medical equipment"; and it must be "appropriate for use in the home." 42 U.S.C. § 1395x(n); 42 C.F.R. § 414.202. The Seating System meets each of these criteria, and OrthoConcepts advances no serious argument to the contrary.

Moreover, DME unequivocally includes "wheelchairs," see 42 U.S.C. § 1395x(n), and the Seating System serves the same (as well as additional) functions as a wheelchair. OrthoConcepts' own expert admitted that a casual observer might conclude that the product "looks like a wheelchair." HCFAR 96-1 also conforms to congressional intent as expressed in P.L. 101-508, § 4152(c)(4), the interim amendment to 42 U.S.C. § 1395m(a)(4) specifying that customized wheelchairs are DME. The legislative history of this provision shows that Congress intended DME to include "postural control devices"

and "custom molded cushions and inserts, or lateral supports" associated with wheelchairs. H.R. No. 101-881, at 268 (1990), reprinted in 1990 U.S.C.C.A.N. 2017, 2270. In short, it takes no great leap to conclude that congressional intent is well effectuated by treating the Seating System as DME.

Further support for HCFA's view is provided by the American Orthotic and Prosthetic Association, which has stated that the Seating System is a brace only when that term is used "in its most broad sense," and that the items are "more accurately described as a subset of orthoses called seating systems or wheeled mobility devices."

Even assuming that the entire device could alternatively be reasonably construed to satisfy the definition of a brace (which includes only examples of individual braces), there was nothing precluding HCFA from resolving the ambiguity in favor of DME. The district court concluded that equipment that could be categorized as both DME and an

orthotic must be treated as an orthotic based on a portion of the MCM's definition of DME that provides that "[t]here are other items which, although durable in nature, may [sic] fall into other coverage categories such as braces [and other categories]." MCM § 2000.1. We do not read this language as establishing DME as a category of last resort; it does not say, for instance, that any equipment that could be classified as a brace is necessarily not DME. Instead, it uses the term "may," suggesting that the classification of equipment that is both brace-like and durable is left to HCFA. Accordingly, we do not accept OrthoConcepts' argument that HCFA had bound itself to resolve cases of ambiguity on the side of braces.

We also note that in establishing its policy, HCFA has been deliberate. HCFA has on multiple occasions met with OrthoConcepts' representatives, examined the equipment at issue, and given consideration to the statute and regulations as applied to the Seating System and comparable devices. HCFA's

thoroughness belies OrthoConcepts' claim that HCFAR 96-1 is merely a litigating position entitled to no deference under Smiley v. Citibank, N.A., 116 S. Ct. 1730, 1736 (1996).

Finally, the classification of medical equipment for reimbursement purposes is the sort of technical question that generally benefits from HCFA's expertise and experience. See Stowell v. Secretary of Health & Human Servs., 3 F.3d 539, 544 (1st Cir. 1993) (stating that "[c]ourts should not cavalierly discount the value of agency expertise painstakingly garnered in the administration, over time, of programs of remarkable intricacy" and citing cases); Hospital San Jorge v. Secretary of Health, Educ. & Welfare, 616 F.2d 580, 589 (1st Cir. 1980) (Campbell, J., concurring) (stating that "[m]atters of [Medicare] accounting, unless they 'be the expression of a whim rather than an exercise of judgment,' are for the agency" (quoting American Tel. & Tel. Co. v. United States, 299 U.S. 232, 237 (1936))). Given HCFA's expertise in

administering Medicare Part B, the logic of its interpretation, and the consistency of its policy, we conclude that the denial of claims for reimbursement of the Seating System under the brace benefit was not arbitrary or capricious, and thus withstands OrthoConcepts' challenge under 5 U.S.C. § 706(2)(A).

The judgment of the district court is reversed and remanded with instruction to vacate the injunction and to enter judgment for Appellants.

UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

Ann WARDER, Dorothy Bouchoux, Massachusetts Therapeutic Technologies, Inc., Florida Therapeutic Technologies, Inc. and The Orthotics Center, d/b/a Orthoconcepts,

Plaintiffs,

v.

Donna SHALALA, Secretary, Department of Health and Human Services and Bruce Vladeck, Administrator, Health Care Financing Administration,

Defendants.

Civ. A. No. 97-10424-MEL.

United States District Court, D. Massachusetts.

May 7, 1997.

Kelly Law Firm, Atlanta, GA (James B. Kelly, Stephen C. Petrovich, of counsel), Palmer & Dodge L.L.P., Boston, MA (Craig Stewart, Anne Robbins, of counsel), for Plaintiffs.

Donald K. Stern, U.S. Attorney for the District of Massachusetts, Boston, MA (Roberta Brown, of counsel), Department of Health and Human Services Office of General Counsel, Boston, MA (Clifford M. Pierce, of counsel), for Defendants.

MORRIS E. LASKER, District Judge.

Thousands of elderly patients living in nursing homes suffer complete or near-complete musculoskeletal failures which render them immobile. One of the most devastating consequences of the diseases which afflict these patients is the development of multisited contractures, which are frequently so debilitating that the patient's body literally folds into itself. These catastrophically crippled patients also suffer associated complications including spasticity, pressure sores, circulatory problems, and respiratory and urinary infections. Nearly 3000 of these patients have been treated through a process known as "orthotic management," which involves custom-fitting bracing systems in order to ease pain, improve functioning and prevent painful and potentially life-threatening complications.

The plaintiffs in this case are two Medicare beneficiaries residing in long-term care facilities and three companies[1] which manufacture and supply systems of interdependent braces attached to external frames which have been prescribed for the individual plaintiffs. OrthoConcepts has been furnishing these and related devices to catastrophically crippled patients since the late 1980s, during which time there has been uncertainty as to their Medicare coverage. Confusion has centered on whether the OrthoConcepts products are properly classified as "braces" or "durable medical equipment" (DME) under the Medicare Act. The significance of this definitional dispute is that reimbursement under Medicare Part B is available for braces but not for DME provided to persons, like the individual plaintiffs in this case, housed in skilled nursing facilities (SNFs).[2] The

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1. The corporate plaintiffs are all part of the same corporate family and will be referred to collectively as "OrthoConcepts."

2. As this suit involves a debate about characterization, each party attempts to define the terms of the argument in order to secure an advantage. Accordingly, plaintiffs refer to the devices in question as "braces" while defendants call them "seating systems." In this opinion, the OrthoConcepts products will be identified as

Health Care Financing Administration (HCFA) issued a recent ruling which sets forth coverage requirements for braces and classifies the OrthoConcepts systems as DME rather than braces. HCFA Ruling 96-1 thus precludes Medicare reimbursement of the orthotic systems, even though they have been medically prescribed for the individual plaintiffs and other SNF residents, and eliminates the funding source which has provided practically all of OrthoConcepts' income.[3]

Plaintiffs challenge the validity of Ruling 96-1 on the grounds that it was issued in violation of the procedural requirements of the Administrative Procedure Act (APA) and the Social Security Act. They contend further that the Ruling is "arbitrary, capricious

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"bracing systems" or "orthotic systems." This terminology is appropriate since defendants do not, and cannot, deny that these systems perform a bracing function, but instead argue that other structural features of the devices make it inappropriate to view them as braces.

3. All of the patients for whom OrthoConcepts systems have been prescribed reside in long-term care facilities, and the corporate plaintiffs have received between 95 and 99% of their income from Medicare reimbursement. Declaration of Kenneth Greene, C.O. ¶¶ 3, 6.

[ ] or otherwise not in accordance with the law" both because it is inconsistent with Congressional coverage requirements and because it lacks any medical justification. They request a declaration that the Ruling is void and that the OrthoConcepts devices are properly reimbursable as braces under Medicare Part B, and seek to enjoin the defendants from enforcing the Ruling or from otherwise denying claims for reimbursement on the grounds that the items are not braces.[4]

The plaintiffs originally moved for a preliminary injunction. Because the materials submitted on that motion address all issues relevant to a determination on the merits, the case is ripe for final adjudication pursuant to Fed.R.Civ.P 65(a)(2), and the parties have been advised that the present decision will constitute a final determination on the merits.

I.

A. Statutory and Regulatory Background

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4. In the complaint, plaintiffs also request costs and attorneys' fees. This issue has not been briefed, and if plaintiffs wish to pursue it, they should do so by motion.

Medicare is a national health insurance program which consists of two parts. Part A provides coverage of institutional health services for eligible individuals. Part B, at issue here, is a supplemental insurance program that affords coverage of physicians' services and various other health services defined to include DME and orthotics (also known as braces).

The Secretary of HHS is charged with administering the Medicare program and has delegated this authority to the Administrator of HCFA. HCFA contracts with private insurance carriers to administer Part B claims. Four "Durable Medical Equipment Regional Carriers" (DMERCs) are responsible for processing DME, prosthetic and orthotic claims. The carriers make coverage determinations in accordance with the Medicare Act and implementing regulations, as well as with guidelines issued by HHS or HCFA, such as the Medicare Part B Carrier's Manual.

Medicare Part B coverage extends to "medical and other health services," which include orthotics as well as DME. 42 U.S.C. §§ 1395k, 1395x(s). The orthotics provided for by statute are "leg, arm, back and neck braces." 42 U.S.C. s 1395x(s)(9). DME coverage is defined to "include[ ] iron lungs, oxygen

tents, hospital beds, and wheelchairs ... used in the patient's home (including an institution used as his home other than [a hospital or an SNF])...." 42 U.S.C. s 1395x(n).[5] In all cases, Medicare coverage is limited to items that are "reasonable and necessary for the diagnosis or treatment of illness and injury or to improve the functioning of a malformed body member." 42 U.S.C. s 1395y(a)(1)(A).

The implementing regulations and guidelines repeat and elaborate on the statutory provisions concerning orthotics

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5. Neither the statute nor the legislative history explains why DME is covered only when used in the patient's home. Both sides offer the following explanation, which seems the most plausible: hospitals and SNFs can be expected to provide generic items of DME such as hospital beds or oxygen tents for use by all patients, and there is thus no need to reimburse individual patients for DME. The plaintiffs persuasively suggest that this supports their claim that the custom-fitted bracing systems at issue are not DME. Defendants respond, however, that Congress' explicit determination that customized wheelchairs are DME proves conclusively that individually tailored items may be DME. While the proposed explanation for the exclusion of DME coverage in hospitals or SNFs is relevant for what light it sheds on the definition of DME, it is too speculative to establish the validity of either the plaintiffs' or the defendants' positions in this case.

and DME. The controlling regulations simply reiterate the statutory definition, listing "leg, arm, back and neck braces" as orthotic devices. 42 C.F.R. ss 410.36, 414.202. A related regulation defines "orthotic device services" to include "orthopedic devices that support or align movable parts of the body, prevent or correct deformities, or improve functioning." 42 C.F.R. § 410.100(g) (listing comprehensive outpatient rehabilitation facility services). The Medicare Carrier's Manual (MCM) augments this definition by explaining that a brace is "a rigid or semirigid device which is used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body." MCM § 2133.

The regulations define DME as equipment that "(1) [c]an withstand repeated use; (2)[i]s primarily and customarily used to serve a medical purpose; (3) [g]enerally is not useful to an individual in the absence of an illness or injury; and (4)[i]s appropriate for use in the home." 42 C.F.R. § 414.202; see also 42 C.F.R. § 410.38. The MCM expands on this definition in a variety of ways. MCM § 2100.1(A) focuses on the durability requirement, explaining that "[a]n item

is considered durable if it can withstand repeated use, i.e., the type of item which could normally be rented" and distinguishing such items from those which are expendable. This provision goes on to suggest the limits of the DME category by emphasizing that "[t]here are other items which, although durable in nature, [ma]y fall into other coverage categories such as braces...." MCM § 2100.1(A). The MCM also provides for reimbursement of certain supplies and accessories used in conjunction with DME. MCM § 2100.5.

Before the issuance of HCFA Ruling 96-1, the above provisions were the only ones which all carriers were required to follow in determining whether the devices at issue here should be treated as DME or orthotics.

B. Reimbursement History of the OrthoConcepts Products

OrthoConcepts specializes in the use of orthotic management to treat patients with multiple chronic disabilities who have complete or near-complete musculoskeletal failures which render them immobile and cause a variety of secondary complications, including spasticity, pressure sores arid

multisited contractures. Complaint ¶¶ 33, 35. Orthotic management consists in fabricating and custom-fitting braces for the primary purposes of "(1) relief of pain by restricting or limiting motion or weight bearing; (2) immobilization and protection of weak musculoskeletal segments; (3) reduction of axial load; (4) retard[ing] the progression of deformity; and (5) improvement of function. Complaint ¶¶ 31, 32. Orthotics work through the application of force to body segments. Pl. Ex. B, OrthoConcepts Summary Report. The bracing systems OrthoConcepts provides typically consist of several individual braces which function both independently and interdependently and which are attached to an external frame. Declaration of John Makely, M.D. ¶ 23; Pl. Ex. M, Affidavit of James Russ, C.O. ¶ 7. The external frame is used for alignment and support because the patients' bodies are too weak to anchor the braces. Id. OrthoConcepts provides bracing systems only pursuant to physician's prescriptions. Since 1989, OrthoConcepts has furnished braces to more than 2,700 patients. Complaint ¶ 40.

In the late 1980s, OrthoConcepts began selling these systems and receiving reimbursement for the devices as

orthotics under Medicare Part B. Complaint at 1-2. In December 1989, OrthoConcepts' president, Kenneth Greene, wrote to the Region V Chicago office of HCFA seeking to establish a national "L Code"[6] specific to the OrthoConcepts products. Def. Ex. 6. The Chief of the Carrier Operations & Policy Branch in that HCFA office, Stephen Arney, responded by explaining that OrthoConcepts could pursue a national code only by writing to the HCFA Bureau of Policy Development. Def. Ex. 7. He went on to advise Greene that the OrthoConcepts systems were reimbursable, if at all, as DME and not as orthotics, and that Part B coverage for DME extends only to home use. Id.

Arney also issued a letter to all carriers in Region V regarding the coverage status of these systems. He described the products as "molded wheel chair seats and backs, as well as supporting accessories, which purportedly serve an orthotic function" and concluded that they should be classified as DME rather than orthotics. Def. Ex. 8. Arney relied on two earlier memoranda from the HCFA Bureau of Eligibility, Reimbursement

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6. L Codes are standardized codes used to identify orthotics and prosthetics for Medicare reimbursement.

and Coverage (BERC)[7] to reach this conclusion. Id. The first memorandum, written in April of 1987, concludes that a "contoured corrective seat ... used to maintain a wheelchair patient in a comfortable upright position" is not covered under Medicare; it notes that the device is not covered under 42 U.S.C. § 1861s(9) because it is not a leg, arm, back or neck brace. Def. Ex. 4. The second memorandum, written nearly two years later, addresses a similar device and explains that DME is the only statutory category which might cover the equipment. Def. Ex. 5. While these memoranda considered coverage for a device referred to as the Pin Dot Seating System, Arney found their reasoning applicable because he viewed the OrthoConcepts and Pin Dot products as "essentially the same." Def. Ex. 8.[8]

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7. This division of HCFA is now known as the Bureau of Policy Development.

8. The plaintiffs note that Arney's statements were made only to carriers within Region V and could not establish national policy. They also point to later events to prove that Arney's statements did not even reflect national policy. In particular, plaintiffs provide a statement from Gezald Blank, M.D., former Medical Director for Region A DMERC, detailing the development of policy concerning coverage of seating systems. Blank states that prior to 1993, no national policy existed which classified seating systems

In February 1990, the Medicare carrier for Ohio, Nationwide Insurance, advised OrthoConcepts of its intent to follow the Region V directive by classifying the OrthoConcepts systems as DME rather than orthotics. Def. Ex. 9, Nationwide later wrote the corporate plaintiffs to explain that their products were not covered under Medicare because they were not primarily used for a medical purpose but served a "convenience, comfort or preventative function." Def. Ex. 10.[9] OrthoConcepts' attorney wrote twice to Nationwide in an

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as either DME or orthotics. Blank Decl. ¶ 8. In 1993, the four DMERC medical directors decided certain seating systems should be considered orthotics and developed billing codes describing these systems. Id. ¶¶ 11, 13. Defendants counter this by explaining that HCFA reversed this policy the following year and determined that the systems should be classified as DME. Supplemental Declaration of Walter Rutemueller ¶ 4. It is important to note that it is undisputed that OrthoConcepts devices are not "seating systems" within the meaning of these billing codes. The parties in this case focus significant energy and attention on coverage determinations, such as those concerning seating systems, which they acknowledge are not directly on point.

9. In their memorandum, defendants state that this letter was written in March 1992, but the copy provided is undated.

effort to get Nationwide to reinstate its earlier decision that the bracing systems were orthotics. Greene Decl. at Ex. 6, 7. The attorney argued that the regional office lacked authority to determine coverage policy; absent a national coverage determination by HCFA, coverage decisions are left to individual carriers rather than to regional offices. Greene Decl. at Ex. 6. The attorney also advised Nationwide that the HCFA Central Office had agreed to write a letter clarifying the carrier's ability to make reimbursement determinations without regard to statements of the regional office. Greene Decl. at Ex. 7. While there is no evidence that HCFA ever sent such a letter, it appears that OrthoConcepts was ultimately successful in its efforts since it continued to be reimbursed for the bracing systems.

OrthoConcepts never received an L Code specific to its product, and accordingly applied for reimbursement by billing for the individual braces provided rather than for the bracing system as a whole. No reimbursement is sought for the external frames to which the braces are attached. OrthoConcepts received reimbursement for its products until December 1994. At that time, the Region A DMERC suspended payments on the grounds that OrthoConcepts had improperly

billed for braces when it was in fact providing wheelchair seating Systems. Def. Ex. 13-14. The Region B and C DMERCs also suspended payments for improper billing. Complaint ¶ 61. When the DMERCs denied all pending reimbursement claims and sought reimbursement of what it determined to have been overpayments to OrthoConcepts, the corporate plaintiffs pursued administrative appeals. The Region A hearing officer ruled that OrthoConcepts' products were DME rather than braces, and upheld the denial of claims. Def. Ex. 20. OrthoConcepts then sought review by an ALJ. On January 3, 1996, the ALJ found that the OrthoConcepts systems "are used for the purpose of supporting a weak or deformed body member or to restrict or eliminate motion in a diseased or injured part of the body" and reversed the hearing officer's decision. Pl. Ex. C. The following month, decisions by a hearing officer in DMERCs B and C held that the OrthoConcepts devices constituted braces rather than DME and reversed the denial of benefits. Pl. Ex. D.

OrthoConcepts' eligibility to receive payments was shortlived, however, since HCFA issued Ruling 96-1, the Ruling presently at issue, on September 18, 1996. The Ruling provides that the

orthotics benefit

> is limited to leg, arm, back, and neck braces that are used independently, rather than in conjunction with, or as components of, other medical or non-medical equipment. It is also held that leg, arm, back and neck braces used in conjunction with, and necessary for the full functioning of, [DME] are accessories to the [DME] ...

HCFA Ruling 96-1-1. The Ruling is binding on all HCFA components, including the ALJs who hear Medicare appeals.

The Ruling offers several illustrations, the first of which purports to address the devices at issue here. The Ruling explains that while these devices "may support or restrict movement in parts of the body," they are not braces within the meaning of the Medicare Act "because they are integral parts of a seating system and are not designed or intended to be used apart from the seating system." HCFA Ruling 96-1-8.

Since all of the patients for whom OrthoConcepts provides bracing systems

reside in long-term care facilities, the Ruling precludes Medicare payment for these systems. The individual plaintiffs are among the many patients who have been or will be effected by this Ruling. Ann Warder recently received an orthotics system which has enabled her to eat and breathe more easily; since this treatment began, her "contractures and condition appear[ ] to have stabilized and not gotten worse, her sores have decreased and she has had fewer health complications." Pl. Ex. G, Declaration of Jane Horner ¶ 6. Her claim for Medicare reimbursement has been denied. Complaint ¶ 53. Dorothy Bouchoux's physician prescribed a bracing system to prevent the painful and potentially life threatening complications that her immobility will otherwise cause. Pl. Ex. J, Declaration of Sam Marthe, M.D. ¶ 13. Orthoconcepts has not filled this prescription because, as a result of the Ruling, it will not be paid. Complaint ¶ 58.

II.

The plaintiffs argue that Ruling 96-1 is invalid because it was issued without providing the public with the notice and opportunity to comment required by both the APA and the SSA. They contend that the SSA mandates notice

and comment because the Ruling changes a substantive legal standard governing the scope of benefits by altering the coverage requirements for orthotics, and that notice and comment are required by the APA since the Ruling is substantive rather than interpretive. They claim that the rule is substantive both because it changes coverage criteria and because of its binding nature.

The government answers that notice and comment were not required under either the APA or the SSA because the Ruling is purely interpretive, that it simply reflects long-standing HCFA policy regarding the respective coverage of the DME and orthotics categories, and that it is an interpretive rule since it "merely advises the public" of HCFA's position.

The plaintiffs argue further that the Ruling is invalid because it is arbitrary and capricious. They claim that because the statute is unambiguous as to the coverage of braces, it needs no interpretation. In particular, they contend that the statutory provision for coverage of braces, limited solely by the general requirement in § 1395y(a)(1)(A) that the devices be "reasonable and necessary ... to improve the functioning of a malformed body member," leaves no room for the limitations imposed by

Ruling 96-1, and that, in any event, the Ruling has no medical justification.

The government responds that the Ruling is at least a permissible, and arguably the most reasonable, interpretation of the relevant provisions of the Medicare Act. The defendants maintain that since Congress has never explicitly addressed the type of bracing system at issue, the agency's determination of the coverage status of these bracing systems is entitled to deference. They argue that while the devices may fit the preruling definition of braces, they can also be considered integral components of DME since they are useful only when attached to an item of DME. The government concludes that it is reasonable to resolve the ambiguity thus created by classifying the devices as DME.

A remaining dispute concerns the proper classification of the OrthoConcepts devices under the criteria existing prior to the Ruling. Because there is considerable overlap between this and the two previous questions, the parties do not focus directly on this issue but address it as part of their other arguments. For example, in debating the need for notice and comment, the parties focus on the reimbursement

policies in effect before the Ruling as part of a dispute over whether the Ruling conforms to long-standing HCFA policy. Similarly, the analysis of whether the Ruling is arbitrary and capricious devotes much attention to interpreting the statutory and regulatory provisions regarding coverage of braces and DME.[10]

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10. Defendants also raise a jurisdictional question. In their answer, filed after argument on the pending motion had been heard, defendants deny that this court has jurisdiction under 28 U.S.C. § 1331, and assert two affirmative defenses based on plaintiffs' failure to satisfy the presentment requirement of 42 U.S.C. §§ 405(g) and 1395ff and the venue requirement of § 405(g). While the defendants did not move to dismiss this case for lack of jurisdiction, and the parties have not briefed this issue, I will address the issue briefly. The government raises these affirmative defenses only as to the corporate plaintiffs and Dorothy Bouchoux, not as to Ann Warder. Thus, even if these affirmative defenses were meritorious, they would not warrant dismissing the case in its entirety. Moreover, it appears that the First Circuit allows courts to entertain claims under § 1331 challenging the methodology used in making coverage decisions. In Bowen v. Michigan Academy of Family Physicians, 476 U.S. 667, 106 S.Ct. 2133, 90 L.Ed.2d 623 (1986), the Supreme Court held that jurisdiction existed under § 1331 for "challenges to the validity of the Secretary's instructions and regulations." Some circuits have held that the reasoning of the Michigan Academy court is no longer applicable in light of the 1986 amendments to § 1395ff which allow judicial review of agency

III.

A. Notice and Comment Requirement

The APA requires all federal agencies to publish proposed rules in the Federal Register in order to provide the public with notice and an opportunity to

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decisions denying Part B coverage through the Medicare Act itself. See, e.g., Farkas v. Blue Cross & Blue Shield of Mich., 24 F.3d 853 (6th Cir.1994) (finding no federal question jurisdiction since Part B claims are now, like Part A claims, reviewable under the Medicare Act). The First Circuit has taken a different approach to the need to unify treatment of Part A and Part B challenges. In McCuin v. Secretary of HHS, 817 F.2d 161 (1st Cir.1987), the First Circuit explained that the reasoning of Michigan Academy is applicable to Part A claims and held that federal question jurisdiction is available for challenges to procedures used in making Medicare determinations, but not to the amount of such determinations. The court in Griffith v. Bowen, 678 F.Supp. 942 (D.Mass.1988) confirmed that federal question jurisdiction remains available for challenges to the manner in which Medicare Part B determinations are made. 678 F.Supp. at 945 ("There is no conflict between the decision in Michigan Academy and Congress' subsequent grant of jurisdiction to review certain Medicare Part B determinations in the 1986 Act."). Furthermore, because the Ruling is binding on all levels of HCFA, it would be futile to require the plaintiffs to pursue this challenge administratively before allowing it to be brought in federal court.

comment. 5 U.S.C. §§ 553(b), (c). The statute exempts "interpretative rules, general statements of policy [and] rules of agency organization, procedure or practice" from these requirements. 5 U.S.C. § 553(b)(3)(B). Reviewing courts are instructed to "hold unlawful and set aside agency action [ ] found to be [ ] without observance of procedure required by law." 5 U.S.C. § 706(2)(D). It is undisputed that Ruling 96-1 is a rule within the meaning of the APA, and that HCFA did not provide a notice-and-comment period. The only question, therefore, is whether the Ruling is an interpretive rule or a substantive rule.

The interpretive rules exception, like all exceptions to the § 553 requirements, is to be "narrowly construed and only reluctantly countenanced." San Diego Air Sports Ctr., Inc. v. FAA, 887 F.2d 966, 969 (9th Cir.1989) (citation omitted). This principle serves Congressional expectations by ensuring that the notice-and-comment requirement fulfills its primary functions of "reintroduc[ing] public participation and fairness to affected parties" into the rule-making process, Batterton v. Marshall, 648 F.2d 694, 703 (D.C.Cir.1980), and "of assuring that an agency's decisions will be informed and responsive," New Jersey

Department of Environmental Protection v. EPA, 626 F.2d 1038, 1045 (D.C.Cir.1980).

Substantive, or legislative, rules are those which "create[ ] rights, assign [ ] duties, or impose[ ] obligations, the basic tenor of which is not already outlined in the law itself." La Casa Del Convaleciente v. Sullivan, 965 F.2d 1175, 1178 (1st Cir.1992). In contrast, interpretive rules merely clarify existing law and "advise the public of the agency's construction of the statutes and rules which it administers." Id. A substantive rule carries the force of law, but an interpretive rule "creates no law and has no effect beyond the statute." Id. That is, while legislative rules are binding and "narrowly constrict the discretion of agency officials" interpretive rules "are not determinative [and do not] foreclose alternate courses of action or conclusively affect rights of private parties." Batterton, 648 F.2d at 702.

An interpretive rule may thus be distinguished from a substantive rule both by its legal effect--is it advisory or mandatory?--and by its content-- does it clarify or create law? A recent Supreme Court decision implies that either of these features may be sufficient to trigger the APA's procedural requirements, i.e., that

notice and comment are required either if a rule is to have the force of law, or if the rule changes existing law. Shalala v. Guernsey Memorial Hospital, 514 U.S. 87, 115 S.Ct. 1232, 131 L.Ed.2d 106 (1995). There, the Court explained that interpretive rules "do not have the force and effect of law" and are issued "to advise the public" of an agency's understanding of the governing law. 115 S.Ct. at 1239. The Court went on to observe that, in any event, notice and comment "would still be required if [the rule] adopted a new position [which] effect[ed] a substantive change in the regulations." Id.

1. Substantive Change

As explained above, plaintiffs claim that HCFA Ruling 96-1 is a substantive rule since it changes the coverage criteria for braces, while the defendants maintain that the Ruling comports with longstanding HCFA policy. Rules which change existing regulatory schemes are substantive, not interpretive. Compare Mt. Diablo Hosp. Dist. v. Bowen, 86C F.2d 951, 956 (9th Cir.1988) (HHS policy on timing of payments represented a "change in law and policy" requiring notice and comment) with Prof'ls and Patients for Customized Care v. Shalala, 56 F.3d 592, 602 (5th Cir.1995) (FDA compliance

policy guide which "does not plow new legal ground" is not substantive). Thus, if the instant Ruling changes the prior regulatory scheme with respect to coverage of braces and DME, it is a substantive rule.

The Ruling limits coverage for orthotics to those braces "used independently, rather than in conjunction with, or as components of, other medical or non- medical equipment." None of the materials which the government cites as evidence of the constancy of its policy even suggest, much less compel, the Ruling's exclusion of coverage for braces which are used along with other equipment. While the Ruling describes itself as a clarification of "long-standing policy," it is significant that it cites no authority setting forth any prior policy of covering only stand-alone devices as braces.

In the absence of any evidence that HCFA had previously adopted the precise limitation set forth in the Ruling, the government cites various memoranda and letters to bolster its argument that "HCFA has consistently maintained, since as early as April 1987, that 'contoured corrective seats' and other supportive modifications to wheelchairs are reimbursable as DME, not as orthotics."

Defendants' Memorandum in Opposition to Plaintiffs' Motion for Preliminary injunction at 23-24; Def. Ex. 2-10. This evidence does not support the government's claim that the Ruling conforms to consistent HCFA policy, however, since these materials evince a very different approach to coverage than that found in the Ruling.

The Ruling neither questions the medical function of the devices in question, nor denies that braces used in conjunction with other equipment continue to serve an orthotic function. Instead, it carves out a per se exception to the orthotics benefit, denying coverage for braces which are not used on a stand-alone basis. Essentially, the Ruling accepts that the devices it considers are braces, but takes the position that they are only covered as such when used independently of other equipment. The Ruling thus decrees that Medicare coverage of braces is limited to braces which meet certain requirements -- requirements which have never been promulgated before.

In contrast to the government's present rationale, the materials on which it relies found the devices under consideration not to be braces, and questioned whether the devices served any

medical purpose at all. For example, the government cites two memoranda from officials of BERC regarding coverage for "seating systems" "used to maintain a wheelchair patient in a comfortable upright position." Def. Ex. 4, 5. The first states that Medicare does not cover the seating systems, and notes that "it is clear they are not a leg, arm, back or neck brace and therefore would not be covered [as an orthotic] either." Def. Ex. 4. Despite the government's present claims, this letter does not classify the devices as DME but instead deems them to be outside the Medicare reimbursement scheme. The second memorandum suggests that the seating systems might be covered as DME, but warns that local carriers making coverage determinations may be concerned that the equipment serves "convenience functions" rather than "medical purposes." Def. Ex. 5. There is no suggestion that the devices meet the definition of braces but are nonetheless excluded from coverage because of the way in which they are used; indeed, there is no consideration given to the fact that the devices are used in conjunction with other equipment.[11] It is also worth

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11. While these materials do not explain the basis for their coverage determinations, the rationale that emerges is that the devices are not braces, see Def. Ex. 4, 7, 8, 9, 10; that

noting that one of these documents indicates that there is "no established national policy on items such as [the seating system]." Def. Ex. 5.

Before the Ruling, the OrthoConcepts devices satisfied all the statutory and regulatory prerequisites for coverage as braces and were reimbursed as such.[12] Now that the Ruling is in place, the plaintiffs cannot receive reimbursement for their bracing systems. In effect, the Ruling carves out an exception from the general statutory provision for coverage of braces. In this manner, the Ruling resembles the regulations at issue in Linoz v. Heckler, 800 F.2d 871 (9th Cir.1986), Cedars-Sinai Medical Center v. Shalala, 939 F.Supp. 1457 (C.D.Cal.1996) and In Home Health Care,

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they might be DME, see Def. Ex. 5, 7, 8, 9; but that they may not serve any medical purpose at all, see Def. Ex. 4, 10.

12. While the defendants argue that HCFA had a longstanding policy of treating the OrthoConcepts systems as DME rather than braces, they do not contend that the bracing systems failed to satisfy any element of the statutory or regulatory definitions of orthotics. Instead, the agency claims that the devices meet the relevant definitions of DME and maintains that the devices are properly classified as DME since they "can be used only as components of or physical attachments to DME."

Inc. v. Bowen, 639 F.Supp. 1124 (D.D.C.1986). In Linoz, the court invalidated a section of the MCM which "carved out a per se exception" to a rule providing for coverage of ambulance service to the "nearest institution with appropriate facilities" by precluding consideration of the availability of a specialist in determining whether facilities were appropriate. 800 F.2d at 877. The court concluded that "[t]he provision withdrew coverage previously provided and thus effected a change in existing law or policy' " which required notice and comment. Id. Similarly, in Cedars-Sinai, the court determined that a section of the MCM which precluded coverage of medical devices not approved for marketing by the FDA was a substantive rule. The court explained that while HCFA may have had a "general policy" of not covering such devices before the MCM provision was enacted, the provision was a substantive change because the previous policy allowed case-by-case evaluations while the MCM section "categorically excluded [the devices] from coverage." 939 F.Supp. at 1465. In In Home Health Care, the court found an HHS rule precluding home health providers from representing beneficiaries in appeals to be a substantive rule. The court observed that "[n]either the underlying statute nor the duly

promulgated regulation ... contains even a hint" of the rule, and that it, "in effect, adds a fifth standard to the four criteria [in the] regulation." 639 F.Supp. at 1126-27. See also Perales v. Sullivan, 948 F.2d 1348, 1354 (2d Cir.1991) ("There can be no question that the assurance requirement was a substantive regulation. It precluded what would otherwise have been a valid claim for federal reimbursement."); Ohio Dep't of Human Servs. v. HHS, 862 F.2d 1228, 1235 (6th Cir.1988) ("The [amendment] was in no way compelled by the original regulation.").

The decisions of the ALJ and the hearing officer finding the OrthoConcepts devices reimbursable as braces lend significant support to plaintiffs' claim that the Ruling is a substantive change from, rather than a restatement of, the earlier definition of braces. The government argues that plaintiffs cannot rely on these decisions. Because HCFA has the authority to issue rulings which are contrary to previous ALJ decisions and which bind ALJs in future cases, the defendants claim that such rulings "do[ ] not constitute a change of course." Def. Mem. at 24-25. The government cites Wilkins v. Sullivan, 889 F.2d 135 (7th Cir.1989) to support its

position.[13] [FN13] However, Wilkins does not hold that ALJ decisions are wholly irrelevant to determining whether an agency has changed course, but only that, under the particular facts before the court, issuance of a HCFA Ruling contrary to some previous ALJ and Appeals Council decisions did not effect such a change. The Wilkins court emphasized that the Secretary had made clear, consistent policy statements both before and after the relevant ALJ and Appeals Council decisions, 889 F.2d at 137-38, 140-41, and that the "ALJ and Appeals Council had not adopted a consistent policy," 889 F.2d at 141.

Here, the facts are quite different. Prior to issuance of Ruling 96-1, neither HHS nor HCFA had made any statement limiting coverage of orthotics to braces used independently. Accordingly, the

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13. The issue in that case was not whether notice and comment were required, but whether the ruling was such an "abrupt change" as to be impermissible. By citing Wilkins, the government shifts the focus to HCFA's "authority" to issue such rulings. This focus is misleading since no claim is made here that ALJ decisions preclude contrary HCFA rulings (so long as HCFA complies with necessary procedures and the rulings are consistent wish the statutory and regulatory framework) Accordingly, the analysis here focuses on whether such rulings may constitute a substantive change.

question is whether such a policy can nonetheless be found in earlier pronouncements of the agency. The decisions of the ALJ and hearing officer are undoubtedly germane to this question. One need not suggest that these decisions established agency policy to see them as pertinent to interpreting the earlier policy. See Ohio Dep't of Human Servs., 862 F.2d at 1235 ("[C]ontemporaneous expressions of opinion by low-ranking officials [are] highly relevant and material evidence of the general understanding of ambiguous regulatory provisions.") This case is very similar to Ohio Department of Human Services. There, the Department of Health, Education and Welfare first announced its position in 1976, and the court was faced with the question whether that position was consistent with earlier regulations. 862 F.2d at 1230-1231, 1234-35. The court relied on a 1974 decision by a regional office--which HEW argued was "erroneous" and thus of "no significance"--in finding that HEW's later position had not been implicit in the earlier regulations. 862 F.2d at 1231, 1234. Here, too, the government asks that "contemporaneous expressions of opinion" be ignored in determining whether a new ruling is consistent with prior regulations. Here, too, these expressions are "highly relevant and

material evidence" of the meaning of the prior regulations. Given the defendants' inability to point to any statute, regulation, or other written provision which the decisions of the ALJ and hearing officer contravened, these decisions provide strong support for the claim that Ruling 96-1 adds a new limitation to the regulatory definition of braces.

Plaintiffs have submitted numerous affidavits, letters and declarations from persons working in the field of orthotics to the effect that HCFA Ruling 96-1 represents a change in law and policy.[14]

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14. The materials plaintiff submitted include a letter sent to HCFA by the Alzheimer's Association, American Rehabilitation Association, Brain Injury Association, Center on Disability and Health, Epilepsy Foundation of America, National Association for the Advancement of Orthotics and Prosthetics, National Multiple Sclerosis Society, National Osteoporosis Foundation, National Stroke Association, Paralyzed Veterans of America, Parkinson's Disease Foundation, Spina Bifida Association of America, and United Cerebral Palsy Associations. These organizations assert that Ruling 96-1 does not reflect longstanding HCFA policy but embodies a substantive change since it results in the denial of coverage for several types of braces used in conjunction with other equipment which were previously covered and reimbursed as orthoses. The letter requested rescission of the Ruling and asked for notice and an

While these materials are certainly not dispositive, they are persuasive because it is implausible that there could have been a longstanding national policy of the type asserted here which was unknown to those working in the field.

2. The Binding Nature of the Ruling

The fact that the Ruling is binding at all administrative levels and leaves HCFA agents no discretion is a further reason to view it as substantive. As the Fifth Circuit recently observed,

> A touchstone of a substantive rule is that it establishes a binding norm.... The key inquiry ... is the extent to which the challenged policy leaves the agency free to exercise its discretion ... in an individual case, or on the other hand, whether the policy so fills out the statutory scheme that upon application one need only determine whether a given case is within the rule's criteria.

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opportunity to comment on any further policy changes in that area.

v. Shalala, 56 F.3d 592, 596 (5th Cir.1995) (citation omitted). Compare W.C. v. Bowen, 807 F.2d 1502, 1505 (9th Cir.1987) ("Rules which substantially limit an agency's discretion are generally substantive rules.") and Duggan v. Bowen, 691 F.Supp. 1487, 1514 (D.D.C.1988) (rule that binds fiscal intermediaries and "prospectively determines coverage determinations" is substantive rule) with American Ambulance Serv. of Pa. v. Sullivan, 716 F.Supp. 861, 871 (E.D.Pa.1989) (provisions which "on their face do nothing more than provide non-binding guidance [and] do not foreclose alternate courses of action" are interpretive rules), rev'd on other grounds, 911 F.2d 901 (3d Cir.1990).

In Levesque v. Block, 723 F.2d 175, 182 (1st Cir.1983), the court explained that the critical question to be answered in determining whether notice and comment are required is whether a rule "was meant to have legislative effect." The rule at issue concerned the definition of the term "household" in food stamp regulations. In finding that notice-and-comment rulemaking were needed, the court emphasized that "[i]t is inconceivable" that the agency would have allowed a state to depart from the definition in the rule. 723 F.2d at 183. The court contrasted this with agency

pronouncements which "purport[ ] to be only advisory" and thus may be deemed interpretive. Id. at n. 3.

Moreover, it is appropriate to consider whether the public will be bound by a rule in determining whether the agency must allow public participation in the rule's development. Exemptions to the s 553 procedures "should be recognized only where ... the need [for public participation] is too small to warrant [it], as for example, when the action in fact does not conclusively bind the agency, the court, or affected private parties." Batterton v. Marshall, 648 F.2d 694, 704 (D.C.Cir.1980) Cf. La Casa del Convaleciente v. Sullivan, 965 F.2d 1175, 1179 (1st Cir.1992) (notice and comment "would be overkill" for a gap-filling rule which set forth "a limited remedy for a limited period of time").

The Ruling at issue here is, by its own terms and by regulation, "binding on all HCFA components, its intermediaries and carriers." HCFA Ruling 96-1; 42 C.F.R. § 401.108. There is no question that this Ruling prevents carriers, hearing officers, ALJs and the Appeals Council from exercising discretion in individual cases, and conclusively determines that the OrthoConcepts systems

cannot be reimbursed as braces. The government does not deny that the Ruling is binding, but notes that "courts have rejected APA challenges to [other rulings which] are binding on all agency adjudicators." Def. Mem. at 25. The cases which defendants cite do not warrant ignoring the binding effect of the Ruling. None of those cases even considers whether the binding nature of a rule ought to be a factor, much less explains why it is irrelevant, in determining whether notice-and-comment rulemaking is required for a particular rule. Two of the cases -- Wilkins v. Sullivan, 889 F.2d 135 (7th Cir.1989) and Kennedy v. Shalala, 995 F.2d 28 (4th Cir.1993)--do not even involve the question whether a ruling is interpretive or substantive.

3. Substantial Impact

Plaintiffs suggest further that the substantial impact which the Ruling has on members of the public should be considered in determining whether the Ruling is substantive. The government argues that the impact of a rule "should no longer be considered a relevant factor in the APA analysis." Def. Mem. at 27. The defendants explain that recent Supreme Court decisions -- Shalala v. Guernsey Memorial Hospital, 514 U.S. 87,

115 S.Ct. 1232, 131 L.Ed.2d 106 (1995) and Reno v. Koray, 515 U.S. 50, 115 S.Ct. 2021, 132 L.Ed.2d 46 (1995)--have upheld agency statements as interpretive without considering the impact of the rules.

According to the First Circuit, "whether a rule has a substantial impact may be relevant in construing the intent of the agency in issuing the rule." Levesque, 723 F.2d at 183. The impact of a rule on the public is germane to this inquiry because the APA's concern with public participation is most deeply implicated where the public impact is greatest. While the defendants note that other circuits have moved away from this view, the First Circuit has not. Nor is it appropriate to renounce this analysis based on the silence of Guernsey and Koray; it is too speculative to conclude that the Supreme Court intended to reject this factor in all circumstances.

Here, the government does not dispute that the Ruling's impact on the public is substantial. As described above, the orthotic systems prescribed for plaintiffs Warder and Bouchoux are of critical importance to their treatment. Many other catastrophically crippled patients are in similar need of this treatment. See Makely Decl. p 25 ("Without access to the braces provided

by OrthoConcepts, thousands of patients in long term care facilities will suffer painful and potentially life threatening complications ...").

* * *

Accordingly, because the Ruling effects a substantive change in the coverage of orthotics, because it is binding on the agency and on the public, and because it has a substantial impact on the public, I find the Ruling to be a substantive rule subject to the procedural requirements of 5 U.S.C. s 553(b) and (c).

As indicated above, plaintiffs also argue that the Ruling was issued in violation of the SSA notice-and-comment requirement. The SSA directs agencies to provide notice-and-comment periods for rules that "establish[ ] or change [ ] a substantive legal standard governing the scope of benefits [or] payment for services." 42 U.S.C. § 1395hh(a)(2). The conclusion that HCFA Ruling 96-1 changed the legal standard concerning payment for orthotics is dispositive of this claim. Accordingly, I find the Ruling was subject to the SSA procedural requirements.

Because HCFA did not comply with the

procedural mandates of the APA or the SSA in issuing Ruling 96-1, the Ruling is invalid.

B. Arbitrary and Capricious Standard

In light of the determination that HCFA Ruling 96-1 is procedurally invalid, there is no need to examine its substantive validity. It is to be expected that a notice-and-comment period will allow HCFA the opportunity to conduct a more comprehensive evaluation of these and related devices. The development of a medical basis for the classification at issue here will be useful in analyzing any challenge to a re-enactment of the Ruling.

C. Application of the Pre-Ruling Standards

The government does not now deny that the OrthoConcepts devices serve a bracing function. The plaintiffs offered undisputed orthotic and medical testimony from specialists in the orthotics field affirming that OrthoConcepts systems satisfy all elements of the prior regulatory definitions of braces. They are "made from rigid and semi-rigid materials," and are "used to support weak or deformed body parts arid restrict motion in a patient's diseased or injured

part of the body." Pl.Ex. M, Russ Aff. ¶ 6; Makely Decl. ¶ 22; Blank Decl. ¶ 18; cf. MCM § 2133.

While the defendants have not argued in their papers or at the hearing that the bracing systems fail to satisfy the definition of orthotics, nor offered testimony from medical or orthotic experts opining that these devices are not braces, they do submit two exhibits which, they suggest, indicate that the systems do not qualify as orthotics.[15] One is a declaration from Walter N. Brach, Jr., who investigated the OrthoConcepts devices for the DMERC A carrier, which was presented in an earlier proceeding. Brach opined that the OrthoConcepts devices are not braces but are "seating systems [ ] identified [by] the 'K' procedure codes." Def. Ex. 15, Brach Decl. p 9. Because there is no indication that Brach has any expertise in the field of orthotics, and because his analysis is inconsistent with that of the medical expert whose declaration the government offered in this litigation,

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15. Defendants also submitted the series of letters and memoranda regarding coverage of "seating systems" which was discussed previously. Because these letters provide no analysis of whether, or how, the OrthoConcepts systems fail to satisfy the definition of orthotics, they add nothing to the present inquiry.

see Declaration of Robert Zone, M.D. ¶ 10 ("[The K-codes used to bill for seating systems] are not applicable to OrthoConcepts' devices."), I find his opinion neither reliable nor persuasive. The government also submits a 1995 Consensus Statement of the American Orthotic and Prosthetic Association (AOPA) Coding Subcommittee which addresses the appropriate classification for the OrthoConcepts systems, and suggests that the AOPA position is consistent with its own since the AOPA found the OrthoConcepts devices "are not described explicitly under the L-codes." Def. Ex. 12 at ¶ 4. However, a more thorough reading of the AOPA Statement supports the plaintiffs' claims. The AOPA stated that the items are "clearly braces by the definition in the MCM," and explained further that they "are more accurately described as a subset of orthoses," that is, a type of brace. Id. at ¶ 1. It seems evident that the AOPA did not believe the absence of a billing code tailored to the OrthoConcepts systems prevented the devices from qualifying as braces.

The government provides no medical basis for the Ruling's reliance on the independence or interdependence of braces as a definitional criteria. In contrast, plaintiffs' experts affirmed that neither

the attachment of braces to an external frame, nor the alignment of braces to allow for interdependent functioning, nor the use of braces in conjunction with a wheeled base, nor the configuring of braces so as to place patients in a seated profile change the primary orthotic function which the OrthoConcepts systems serve. Pl. Ex. M, Russ Aff. ¶¶ 8, 9; Makely Decl. ¶¶ 14-15, 23-24; Blank Decl. ¶¶ 19-21.

Rather than arguing that OrthoConcepts' devices do not satisfy the MCM definition of braces, the defendants submit that many other items--such as hospital beds, crutches and splints--also satisfy this definition. They offer this evidence of the over-inclusiveness of the MCM definition as if to say that the inadequacy of the definition entitles them free rein to exclude items from its coverage. The defendants do not use orthotic or medical principles to guide their classification decisions. In effect, the government's position writers the words "braces" and "orthotics" out of the statute and regulations. These terms are sufficiently definite and meaningful to provide a basis for distinguishing among devices. The appropriate place to look for such a basis is in the orthotic

field.[16] The agency's reliance on the purported inadequacy of its own definition as a basis for excluding devices from coverage is unpersuasive.

Defendants argue further that the devices "can easily be viewed as integral components of DME," and that it is "clearly reasonable for the agency to take the position that devices ... which can be used only as components of, or physical attachments to DME, should be classified for Part B reimbursement purposes as DME." Def. Mem. at 17-18.[17]

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16. Orthotic principles can explain, for example, why a bed is not a brace, even though it may satisfy the MCM definition.

17. The government relies on the deference due agency action in arguing that the principles embodied in the Ruling represent a permissible interpretation of the underlying statute. However, in light of the finding that Ruling 96-1 changes the definition of orthotics, the Ruling can provide no basis for deferring to the agency's current position that the OrthoConcepts devices are properly covered as DME rather than braces under the pre-Ruling regulations. Since this position is unsupported by prior agency pronouncements, it is merely a litigating position to which no deference is due. See Bowen v. Georgetown Univ. Hosp., 488 U.S. 204, 109 S.Ct. 468, 102 L.Ed.2d 493 (1988) ("We have never applied the principle of [Chevron] to agency litigating positions that are wholly unsupported by regulations, rulings, or administrative

One problem with this argument is that while bracing systems fall easily within the definition of orthotics, it requires far more manipulation to force the devices into the definition of DME.

Plaintiffs raise real questions as to whether the bracing systems satisfy two of the four DME requirements set forth in the MCM definition. First, plaintiffs argue that the systems do not meet the durability requirement. The MCM specifies that "[a]n item is considered durable if it can withstand repeated use, i.e., the type of item which could normally be rented." MCM § 2100.1(A). The OrthoConcepts systems are custom-designed for individual patients rather than for repeated use by successive patients. The government replies that Congress has explicitly provided for coverage of certain customized items, most notably customized wheelchairs, as DME. While this shows that there is no per se bar on classifying individually tailored devices

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practice.") The relevant question is thus not whether classification of the OrthoConcepts systems as DME is permitted under the prior regulatory scheme, but whether it is correct. Since the defendants' memorandum contends that the Ruling "arguably adopts the most reasonable interpretation of the statute," I read it to take that position. Def. Mem. at 21.

as DME, the fact that additional regulations are needed to confirm that particular items which are ordinarily covered as DME are considered DME when customized suggests that customization is not part of the generally understood meaning of DME. Second, the plaintiffs contend that the OrthoConcepts devices do not satisfy the requirement that items of DME be suitable for use in the home. They base this argument on the fact that the bracing systems are needed only by patients who are so catastrophically crippled that they require treatment in long-term care facilities, and they note further that the devices must be frequently adjusted. The government responds that nothing prevents use of these devices in the home, and argues that DME covers other items, such as iron lungs and ventilators, which need servicing and which are frequently used to treat patients who require additional care.

Both the ALJ and the hearing officer who evaluated the OrthoConcepts products determined that they did not satisfy the durability and home-use requirements of the DME definition. It is not necessary, however, to decide that the bracing systems do not satisfy the DME definition in order to conclude that the government cannot use a purported ambiguity created

by the devices falling within two coverage categories to classify them as DME. The MCM definition of DME provides that "[t]here are other items which, although durable in nature, [ma]y fall into other coverage categories, such as braces, prosthetic devices, artificial arms, legs, and eyes." MCM § 2100.1(A). Given that the listed items are all reimbursable in their own right, a clear implication of this provision is that patients may be reimbursed for these items under the relevant coverage category regardless of whether they also satisfy the requirements of DME. That is, if an item is otherwise classified, it is not considered DME. As Gerald Blank, M.D., former medical director of DMERC A, testified at a hearing on the OrthoConcepts products, "[e]ven if [the device met the DME] criteria, which it does not, it is classified under another heading and therefore would not be considered DME for that reason additionally." Pl. Ex. E, 219:4-7.

This is the most logical way to understand this provision because the definition of DME is so broad that it could otherwise render other coverage categories meaningless. The government's argument could apply equally well to nearly any medical device which is not

expendable, including all braces and prosthetics. Accepting such an argument would permit the government to define any such item as DME, thereby limiting coverage to home use. In effect, this would allow HCFA to simply write various coverage categories out of the statute. The MCM provision clarifies that items are covered as DME only where no other coverage provision is applicable.

The government's argument that the bracing systems are properly covered as DME provides no basis for distinguishing the systems from independent braces, since bracing systems fit the definition of DME no better than any other type of brace. Nor can the defendants rely on the attachment of the OrthoConcepts braces to an external frame to justify treating these bracing systems differently from other braces; such reliance misconceives the relationship between the braces and the external frame and wheeled base.

The government vacillates between arguing that the bracing systems are themselves DME and claiming that their attachment to wheeled seating systems makes them accessories to DME. The suggestion that the bracing systems are accessories to DME misses an important distinction. There is a

difference between devices which enable DME to serve its primary function--for example, an anti-tip device which helps a wheelchair provide transportation--and those which are attached to DME in order to perform their own primary functions--for example, an IV pole which is attached to a wheelchair for convenience. Only the former type of device is properly considered an accessory which is "necessary for the effective use of [DME]." See MCM § 2100.5; Blank Decl. ¶ 14. The OrthoConcepts devices fall into the latter category and thus are properly reimbursable for their own medical function and not as accessories to DME. See Makely Decl. ¶¶ 14, 23 ("Using a brace in conjunction with a piece of medical or non-medical equipment including wheelchairs, in no way changes the primary function of a brace .... the function of the [OrthoConcepts] brace is not dependent on attachment to any external superstructure.") Moreover, it is questionable whether the external frame and wheeled base to which the braces are attached can be considered DME. Items of DME must be "primarily and customarily used to serve a medical purpose." MCM § 2100.1. The frame and base perform no independent medical role beyond fostering the proper orthotic functioning of the bracing systems. See

Blank Decl. ¶¶ 19-21.

* * *

Because the OrthoConcepts products satisfy the statutory and current regulatory definition of orthotics, and because there is no medical or orthotic basis for denying coverage to braces which are used in conjunction with other equipment, I find the OrthoConcepts systems are reimbursable as braces under the Medicare Part B orthotics benefit. Accordingly, the plaintiffs' prayer for an injunction restraining defendants from denying reimbursement for these devices on the grounds that they are not braces is granted.

In sum, plaintiffs' request for a declaration that HCFA Ruling 96-1 is void for failure to comply with the procedural requirements of the APA and the SSA is granted, for a declaration that Ruling 96-1 is void as arbitrary and capricious is not reached, for a declaration that the OrthoConcepts systems are reimbursable as braces under the Medicare Part B orthotics benefit is granted, and for an injunction preventing defendants from enforcing the Ruling or otherwise denying claims for reimbursement on the ground that the OrthoConcepts systems are not braces is granted.

Submit proposed decree on notice.

UNITED STATES CODE ANNOTATED
TITLE 42. THE PUBLIC HEALTH AND WELFARE
CHAPTER 7--SOCIAL SECURITY
SUBCHAPTER XVIII--HEALTH INSURANCE FOR AGED AND DISABLED
PART D--MISCELLANEOUS PROVISIONS

§ 1395x. Definitions

For purposes of this subchapter-

...

(n) Durable medical equipment

The term "durable medical equipment" includes iron lungs, oxygen tents, hospital beds, and wheelchairs (which may include a power-operated vehicle that may be appropriately used as a wheelchair, but only where the use of such a vehicle is determined to be necessary on the basis of the individual's medical and physical condition and the vehicle meets such safety requirements as the Secretary may prescribe) used in the patient's home (including an institution used as his home other than an institution that meets the requirements of subsection (e)(1) of this section or section 1395i-3(a)(1) of this title), whether furnished on a rental basis or purchased, and includes blood-testing strips and blood glucose

monitors for individuals with diabetes without regard to whether the individual has Type I or Type II diabetes or to the individual's use of insulin (as determined under standards established by the Secretary in consultation with the appropriate organizations); except that such term does not include such equipment furnished by a supplier who has used, for the demonstration and use of specific equipment, an individual who has not met such minimum training standards as the Secretary may establish with respect to the demonstration and use of such specific equipment. With respect to a seat-lift chair, such term includes only the seat-lift mechanism and does not include the chair.

UNITED STATES CODE ANNOTATED
TITLE 42. THE PUBLIC HEALTH AND WELFARE
CHAPTER 7--SOCIAL SECURITY
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PART D--MISCELLANEOUS PROVISIONS

§ 1395x. Definitions

For purposes of this subchapter-

...

(s) Medical and other health services

The term "medical and other health services" means any of the following items or services:

(1) physicians' services;

(2)(A) services and supplies (including drugs and biologicals which cannot, as determined in accordance with regulations, be self-administered) furnished as an incident to a physician's professional service, of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills;

(B) hospital services (including

drugs and biologicals which cannot, as determined in accordance with regulations, be self-administered) incident to physicians' services rendered to outpatients and partial hospitalization services incident to such services;

(C) diagnostic services which are-

(i) furnished to an individual as an outpatient by a hospital or by others under arrangements with them made by a hospital, and

(ii) ordinarily furnished by such hospital (or by others under such arrangements) to its outpatients for the purpose of diagnostic study;

(D) outpatient physical therapy services and outpatient occupational therapy services;

(E) rural health clinic services and Federally qualified health center services;

(F) home dialysis supplies and equipment, self-care home dialysis support services, and institutional dialysis services and supplies;

(G) antigens (subject to quantity

limitations prescribed in regulations by the Secretary) prepared by a physician, as defined in subsection (r)(1) of this section, for a particular patient, including antigens so prepared which are forwarded to another qualified person (including a rural health clinic) for administration to such patient, from time to time, by or under the supervision of another such physician;

(H)(i) services furnished pursuant to a contract under section 1395mm of this title to a member of an eligible organization by a physician assistant or by a nurse practitioner (as defined in subsection (aa)(5) of this section) and such services and supplies furnished as an incident to his service to such a member as would otherwise be covered under this part if furnished by a physician or as an incident to a physician's service; and

(ii) services furnished pursuant to a risk-sharing contract under section 1395mm(g) of this title to a member of an eligible organization by a clinical psychologist (as defined by the Secretary) or by a clinical social worker (as defined in subsection (hh)(2) of this section), and such services and supplies furnished as an incident to such clinical psychologist's services or clinical

social worker's services to such a member as would otherwise be covered under this part if furnished by a physician or as an incident to a physician's service;

(I) blood clotting factors, for hemophilia patients competent to use such factors to control bleeding without medical or other supervision, and items related to the administration of such factors, subject to utilization controls deemed necessary by the Secretary for the efficient use of such factors;

(J) prescription drugs used in immunosuppressive therapy furnished, to an individual who receives an organ transplant for which payment is made under this subchapter, but only in the case of drugs furnished--

(i) before 1995, within 12 months after the date of the transplant procedure,

(ii) during 1995, within 18 months after the date of the transplant procedure,

(iii) during 1996, within 24 months after the date of the transplant procedure,

(iv) during 1997, within 30 months

after the date of the transplant procedure, and

(v) during any year after 1997, within 36 months after the date of the transplant
procedure;

(K)(i) services which would be physicians' services if furnished by a physician (as defined in subsection (r)(1) of this section) and which are performed by a physician assistant (as defined in subsection (aa)(5) of this section) under the supervision of a physician (as so defined) and which the physician assistant is legally authorized to perform by the State in which the services are performed, and such services and supplies furnished as incident to such services as would be covered under subparagraph (A) if furnished incident to a physician's professional service; and but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services,

(ii) services which would be physicians' services if furnished by a physician (as defined in subsection (r)(1) of this section) and which are performed by a nurse practitioner or clinical nurse specialist (as defined in

subsection (aa)(5) of this section) working in collaboration (as defined in subsection (aa)(6) of this section) with a physician (as defined in subsection (r)(1) of this section) which the nurse practitioner or clinical nurse specialist is legally authorized to perform by the State in which the services are performed, and such services and supplies furnished as an incident to such services as would be covered under subparagraph (A) if furnished incident to a physician's professional service, but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services;

(iii), (iv) Repealed. Pub.L. 105-33, Title IV, § 4511(a)(2)(A)(ii), Aug. 5, 1997, 111 Stat. 442

(L) certified nurse-midwife services;

(M) qualified psychologist services; and

(N) clinical social worker services (as defined in subsection (hh)(2) of this section);

(O) erythropoietin for dialysis patients competent to use such drug

without medical or other supervision with respect to the administration of such drug, subject to methods and standards established by the Secretary by regulation for the safe and effective use of such drug, and items related to the administration of such drug;

(P) prostate cancer screening tests (as defined in subsection (oo) of this title);

(Q) an oral drug (which is approved by the Federal Food and Drug Administration) prescribed for use as an anticancer chemotherapeutic agent for a given indication, and containing an active ingredient (or ingredients), which is the same indication and active ingredient (or ingredients) as a drug which the carrier determines would be covered pursuant to subparagraph (A) or (B) if the drug could not be self-administered;

(R) colorectal cancer screening tests (as defined in subsection (pp) of this section); and

(S) diabetes outpatient self-management training services (as defined in subsection (qq) of this section); and

(T) an oral drug (which is approved by the Federal Food and Drug Administration) prescribed for use as an acute anti-emetic used as part of an anticancer chemotherapeutic regimen if the drug is administered by a physician (or as prescribed by a physician)--

(i) for use immediately before, at, or within 48 hours after the time of the administration of the anticancer chemotherapeutic agent; and

(ii) as a full replacement for the anti-emetic therapy which would otherwise be administered intravenously.

(3) diagnostic X-ray tests (including tests under the supervision of a physician, furnished in a place of residence used as the patient's home, if the performance of such tests meets such conditions relating to health and safety as the Secretary may find necessary and including diagnostic mammography if conducted by a facility that has a certificate (or provisional certificate) issued under section 354 of the Public Health Service Act [42 U.S.C.A. s 263b]), diagnostic laboratory tests, and other diagnostic tests;

(4) X-ray, radium, and radioactive isotope therapy, including materials and

services of technicians;

(5) surgical dressings, and splints, casts, and other devices used for reduction of fractures and dislocations;

(6) durable medical equipment;

(7) ambulance service where the use of other methods of transportation is contraindicated by the individual's condition, but only to the extent provided in regulations;

(8) prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices, and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens;

(9) leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacements if required because of a change in the patient's physical condition;

(10)(A) pneumococcal vaccine and its administration and, subject to section

4071(b) of the Omnibus Budget Reconciliation Act of 1987, influenza vaccine and its administration; and

(B) hepatitis B vaccine and its administration, furnished to an individual who is at high or intermediate risk of contracting hepatitis B (as determined by the Secretary under regulations);

(11) services of a certified registered nurse anesthetist (as defined in subsection (bb));

(12) subject to section 4072(e) of the Omnibus Budget Reconciliation Act of 1987, extra-depth shoes with inserts or custom molded shoes with inserts for an individual with diabetes, if--

(A) the physician who is managing the individual's diabetic condition (i) documents that the individual has peripheral neuropathy with evidence of callus formation, a history of pre-ulcerative calluses, a history of previous ulceration, foot deformity, or previous amputation, or poor circulation, and (ii) certifies that the individual needs such shoes under a comprehensive plan of care related to the individual's diabetic condition;

(B) the particular type of shoes are prescribed by a podiatrist or other qualified physician (as established by the Secretary); and

(C) the shoes are fitted and furnished by a podiatrist or other qualified individual (such as a pedorthist or orthotist, as established by the Secretary) who is not the physician described in subparagraph (A) (unless the Secretary finds that the physician is the only such qualified individual in the area);

(13) screening mammography (as defined in subsection (jj) of this section);

(14) screening pap smear and screening pelvic exam; and

(15) bone mass measurement (as defined in subsection (rr) of this section).

No diagnostic tests performed in any laboratory, including a laboratory that is part of a rural health clinic, or a hospital (which, for purposes of this sentence, means an institution considered a hospital for purposes of section 1395f(d) of this title) shall be included within paragraph (3) unless such

laboratory--

(16) if situated in any State in which State or applicable local law provides for licensing of establishments of this nature, (A) is licensed pursuant to such law, or (B) is approved, by the agency of such State or locality responsible for licensing establishments of this nature, as meeting the standards established for such licensing; and

(17)(A) meets the certification requirements under section 353 of the Public Health Service Act [42 U.S.C.A. s 263a]; and

(B) meets such other conditions relating to the health and safety of individuals with respect to whom such tests are performed as the Secretary may find necessary.

There shall be excluded from the diagnostic services specified in paragraph (2)(C) any item or service (except services referred to in paragraph (1)) which would not be included under subsection (b) of this section if it were furnished to an inpatient of a hospital. None of the items and services referred to in the preceding paragraphs (other than paragraphs (1) and (2)(A)) of this subsection which are furnished to a

patient of an institution which meets the definition of a hospital for purposes of section 1395f(d) of this title shall be included unless such other conditions are met as the Secretary may find necessary relating to health and safety of individuals with respect to whom such items and services are furnished.

(4) TREATMENT OF POWER-DRIVEN WHEELCHAIRS AS MISCELLANEOUS ITEMS OF DURABLE MEDICAL EQUIPMENT.

(A) IN GENERAL.-Section 1834(a)(2XA) (42 U.S.C.1395m(a)(2)(A)) is amended -

(i) in clause (i), by inserting "or" at the end;

(ii) in clause (ii), by striking "or" at the end; and

(iii) by striking clause (iii).

(B) CRITERIA FOR TREATMENT OF WHEELCHAIR AS CUSTOMIZED ITEM.-

(i) Section 1834(a)(4) (42 U.S.C. 1395m(a)(4)) is amended by adding at the end the following: "In the case of a wheelchair furnished on or after January 1, 1992, the wheelchair shall be treated as a customized item for. purposes of this paragraph if the wheelchair has been measured, fitted, or adapted in consideration of the patient's body size, disability, period of need, or intended use, and has been assembled by a

supplier or ordered from a manufacturer who makes available customized features, modifications, or components for wheelchairs that are intended for an individual patient's use in accordance with instructions from the patient's physician."

(ii) The amendment made by clause (i) shall apply to items furnished on or after January 1, 1992, unless the Secretary develops specific criteria before that date for the treatment of wheelchairs as customized items for purposes of section 1834(aX4) of the Social Security Act (in which case the amendment made by such clause shall not become effective).

Non-custormized motorized wheelchairs would be recategorized back into the rental cap category of equipment. The option for treating wheelchairs as customized would not be changed.

If the Secretary does not issue regulations defining "customized" wheelchairs by January 1, 1992, a statutory definition would become effective. Under this definition, a customized power driven or manual wheelchair would be defined as a wheelchair which has been: (1) measured, fitted, or adapted in consideration of a patient's body size, disability, length of need or intended use; and (2) has been assembled by the supplier or ordered through a manufacturer who make available customized features, modifications or components that are intended for a specific patient's use in accordance with a physician's order.

In applying this definition, the Committee intends that examples of features that are only available in customized equipment may include, but are

not limited to: (1) semi or full reclining backs, (2) special heights for arms, seats or backs, (3) special width or depth of seat, (4) attachments to convert wheelchairs to one-armed drive, (5) postural control devices, (6) custom molded cushions and inserts, or lateral supports.

This definition would become effective on January 1, 1992, unless the Secretary provides for an alternative definition of customized wheelchairs prior to January 1, 1992, in which case the provision would not be effective.

The Secretary would establish a reasonable useful lifetime of rental equipment, including frequently serviced items. The useful lifetime would be 5 years, unless the Secretary finds, based on program experience, that a longer or shorter period is appropriate for an item. After an item's useful lifetime is reached during a continuous period of medical necessity, the Secretary would provide for
a new cycle of rental payments.

Carriers would be permitted to make exceptions, and begin a new cycle of rental payments, for equipment that is lost or irreparably damaged. Such exceptions would only be authorized after

special consideration and scrutiny of the circumstances by the carrier.

Dept. of Health
& Human Services

HCFA RULINGS

Health Care
Financing Admin.

Ruling No. 96-1 September 1996

HCFA Rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous provisions of the law or regulations relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, and related matters.

HCFA Rulings are binding on all HCFA components, its intermediaries and carriers, including carrier hearing officers, the Provider Reimbursement Review Board, the Medicare Geographic Classification Review Board, the Departmental Appeals Board, and administrative law judges who hear Medicare appeals. These Rulings promote consistency in interpretation of policy and adjudication of disputes.

This Ruling states the policy of the Health Care Financing Administration. regarding the distinction between the statutory benefits of "orthotics" and

"durable medical equipment" under Medicare Part B. The distinction may have an effect on the Medicare approved amount of payment and is necessary in those instances where items are furnished in skilled nursing facilities that meet the definition in section 1819(a)(1) of the Social Security Act (the Act) or hospitals due to the express exclusion from Part B coverage of durable medical equipment when used in a hospital or skilled nursing facility.

The Ruling clarifies that the "orthotics" benefit in section 1861(s)(9) of the Act, insofar as braces are concerned, is limited to leg, arm, back1 and neck braces that are used independently rather than in conjunction with, or as components of, other medical or non-medical equipment. It also clarifies that accessories used in conjunction with, and necessary for the full functioning of durable medical equipment fall. Under the durable medical equipment benefits category. Finally, the Ruling provides several examples that illustrate the application and scope of these two terms.

MEDICARE PROGRAM

Medicare Supplementary Medical Insurance (Part B)

CLARIFICATION OF THE TERMS "ORTHOTICS," "BRACES," AND "DURABLE MEDICAL EQUIPMENT" UNDER MEDICARE PART B

HELD: The "orthotics" benefit described in section 1861(s)(9) of the Social Security Act, insofar as braces are concerned, is limited to leg, arm, back, and neck braces that are used independently, rather than in conjunction with, or as components of, other medical or non-medical equipment. It is also held that leg, arm, back, and neck braces used in conjunction with, and necessary for the full functioning of, durable medical equipment are accessories to the durable medical equipment and, hence, subject to the requirements of section 1861(n) of the Social Security Act.

CITATIONS: Sections 1834(a)(4) and (h) and 1861(n) and (s)(9) of the Social Security Act (42 U.S.C. 1395m(a)(4) and (h) and 1395x(n) and (s)(9); and 42 CFR 414.202.

BACKGROUND

The Medicare program's long-standing policy has been to limit payment for "orthotics" under Medicare Part B to leg, arm, back, and neck braces that are stand-alone devices used independently of other kinds of medical equipment. Recent decisions issued by administrative law judges and Medicare carrier hearing officers have, however, diverged from this policy and have interpreted section 1861(s)(9) of the Act, insofar as braces are concerned, as encompassing all devices that serve to support or restrict motion in a part of the body, even if the devices may not reasonably be used on their own and are primarily intended to be used with other equipment. The purpose of this Ruling is to provide clarification and guidance regarding the scope and meaning of the statutory benefits for "orthotics" and "durable medical equipment."

ORTHOTICS

Section 1834(h) of the Social Security Act (the Act) provides for payment of "orthotics and prosthetics" as described "in section 1861(s)(9)[.]" Section 1861(s)(9) of The Act in turn lists only the following:

(9) leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacements if required because of a change in the patient's physical condition [.]

In light of this limited statutory language, we defined orthotic devices" in 42 CFR 414.202 of our regulations, which states in pertinent part:

Prosthetic and orthotic devices means--

* * * * *

(3) Leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacements if required because of a change in the beneficiary's physical condition. (Emphasis added).

DURABLE MEDICAL EQUIPMENT

In contrast to the very specific wording of section 1861(s)(9) of the Act, section 1861(n) of the Act employs an open-ended reference to what constitutes "durable medical equipment" by stating that the term "includes" items, such as oxygen tents, hospital beds, and wheelchairs, that may be used in the

home. Our definition of durable medical equipment set forth at 42 CFR 414.202, in part, tracks this language by referring in a similarly open-ended manner to medical equipment that can withstand repeated use and is appropriate for use in the home. In light of the breadth of the durable medical equipment category set forth in the statute and regulation, section 2100.5 of the Medicare Carrier's Manual, Part 3 - Claims Process, "Coverage of Supplies and Accessories," provides that payment for durable medical equipment extends to coverage of "supplies and accessories" that are "necessary for the effective use of durable medical equipment."

SEATING DEVICES AS AN EXAMPLE OF DURABLE MEDICAL EQUIPMENT

Many items, including wheelchairs and hospital beds (both expressly classified as durable medical equipment under section 1861(n) of the Act and section 2100.1 of the Medicare Carrier's Manual, Part 3 - Claims Process, "Definition of Durable Medical Equipment") support portions of the body. Other items, such as splints or casts (both classified under section 1861(s)(5) of the Act), protect or restrict movement of a portion of the body. None of these items is

appropriately classified as a "brace" under section 1861(s)(9) of the Act. (We also generally exclude orthopedic shoes or other shoe inserts or supportive devices for the feet from coverage.)

To the extent that a wheelchair seating system or other equipment may or may not function properly or not achieve its full "therapeutic benefit" without attached components supporting or restricting motion in a body part, the attachments are appropriately viewed as a necessary accessory that is an integral part of the durable medical equipment and is, accordingly, payable as durable medical equipment, provided that the other prerequisites for classification as durable medical equipment are met.

Many seating systems (including wheelchairs) incorporate as integral parts various rests and supporting and positional attachments that are modifications of the seating system and that are intended to be used with the seating system to which they are attached. Section 1861(n) of the Act expressly classifies wheelchairs as durable medical equipment. Furthermore, the legislative history and prior Congressional enactments evidence no intent to classify separately integral components or 'attachments to seating

systems as "braces."

Section 4152(c)(4) of the Omnibus Budget Reconciliation Act of 1990 (OBRA 1990), Public Law 101-508, enacted on November s, 1990, amended section 1834(a)(4) of the Act, governing customized durable medical equipment, to extend coverage to customized wheelchairs that have been "measured, fitted, or adapted in consideration" of a patient's "disability" ana including "customized features, modifications, or components" in "accordance with instructions from the patient's physician." The Congress explained that these customized features could "include, but are not limited to" items such as "attachments to convert wheelchairs to one-armed drive," "postural control devices," and "custom molded cushions and inserts or lateral supports." (House Report No. 101-881, 101st Cong., 2d Sess., 1990 USCCAN at 2270.) Thus, ample evidence establishes that the Congress intended sophisticated wheelchairs, including chairs with functional attachments, to be classified in their totality as durable medical equipment.

Even though the Congress was addressing customized wheelchairs, the intent to classify this equipment in its totality as durable medical equipment

extends by analogy to ordinary wheelchairs with attachments. Taken together with the narrow wording of section 1861(s)(9) of the Act, the Congress's treatment of attachments to wheelchairs thus strongly supports the conclusion that a device supporting or restricting motion in a body part but that is an integral part of other equipment is not appropriately classified under the brace benefits category set forth in section 1861(s)(9) of the Act. Our long-standing policy governing the breadth of the durable medical equipment benefits category reflects this congressional intent.

CONCLUSION AND ILLUSTRATIONS

For the reasons set forth above, we therefore conclude that "orthotics" payable under section 1861(s)(9), insofar as braces are concerned, and sections 1834(a) and (h) of the Act are properly limited to leg, arm, back, and neck braces that are stand-alone devices used independently of other kinds of medical equipment. When a device that supports or restricts motion in a part of the body is not generally used, or may not reasonably be used, on its own and is primarily intended to be used with other medical or non-medical equipment payable as durable medical equipment, the durable

medical equipment benefits category, and not the brace benefits category, applies.

Following are three examples that illustrate the application and scope of the terms "orthotics" and "durable medical equipment":

Illustration 1. A supplier manufactures and supplies medical devices to individuals who are generally elderly and suffer from Alzheimer's or other debilitating neuromuscular diseases that have caused them to be nonambulatory, immobile, and confined to a chair or bed. Due to their immobility, these patients may suffer from secondary complications, such as pressure sores, multisited contractures, musculoskeletal degeneration and deformities, and circulatory problems.

Under a physician's order, the supplier furnishes individually fitted attachments designed to be used in conjunction with a chair to seat and position the patient. The attachments, which the supplier labels "orthotic braces," are alleged to position limbs and other body parts properly; restrict motion or weight bearing; immobilize and protect weak musculoskeletal segments; reduce load; retard progression of musculoskeletal deformity; and improve

function. The design of the supplier's "orthotic braces" requires them to be attached to the chair frame, and the "orthotic braces" cannot function or be used apart from the chair to which they are attached.

Discussion: Although the devices in question may support or restrict movement in parts of the body, they are not braces within the meaning of 1861(s)(9) of the Act because they are integral parts of a seating system and are not designed or intended to be used apart from the seating system.

Illustration 2. A supplier furnishes what it describes as a lumbar support cushion comprised of a number of attachment straps and front and back cushions molded to fit the patient's body. The device is alleged to supply corrective support and pressure to the back to address postural defects and conditions such as scoliosis (curvature of the spine). Although capable of being worn separately while standing or lying down, the device is designed to fit into a seated base. In practice, the device is also predominantly worn and used while the patient is seated and is most frequently used by patients who are largely chairbound.

Discussion: Although the device in question may support or restrict movement in parts of the body, it is primarily intended to be used in conjunction with a seat and is comparable to a custom molded cushion or seat insert. The support cushion is accordingly not a brace within the meaning of section 1861(s)(9) of the Act.

Illustration 3. A supplier manufactures a Sophisticated hospital bed with motorized sections that may be individually adjusted to position the patient's body and with straps and lateral support devices that provide support and limit movement of the patient's extremities, including limbs. The bed, with its lateral supports, is used with patients who have suffered severe accident trauma,including potential spinal cord injury, and who must be carefully positioned with limited motion to prevent further injury.

Discussion: Although the lateral supports, straps, and motorized sections support and restrict motion in parts of the body, all of these features are integral parts of a hospital bed, which is classified as durable medical equipment, and these components may therefore not be separately categorized as braces under section 1861(s)(9) of

the Act.

HELD: The "orthotics" benefit described in section 1861(s)(9), insofar as braces are concerned, and sections 1834(a) and (h) of the Social Security Act is limited to leg, arm, back, and neck braces that are used independently, rather than in conjunction with, or as components of, other medical or non-medical equipment. It is also held that leg, arm, back, and neck braces used in conjunction with, and necessary for the full functioning of, durable medical equipment are accessories to the durable medical equipment and, hence, subject to the requirements of section 1861(n) of the Social Security Act.

EFFECTIVE DATE

This Ruling is effective September 18, 1996.

Dated: _____

_____

Bruce C. Vladeck
Administrator,
Health Care Financing
Administration